

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

In Re: National Prescription Opiate Litigation)	MDL No. 1:17-cv-02804
)	
COUNTY OF SUMMIT, OHIO,)	CASE NO. 1:18-op-45090
<i>et al.</i> ,)	JUDGE DAN AARON POLSTER
)	
Plaintiffs,)	MAGISTRATE JUDGE DAVID A. RUIZ
)	
v.)	
)	REPORT AND RECOMMENDATION
PURDUE PHARMA L.P., <i>et al.</i> ,)	
)	
Defendants.)	

On May 25, 2018, the Distributor Defendants,¹ Pharmacy Defendants,² and
Manufacturer Defendants³ filed Motions to Dismiss the Second Amended Complaint. (R. 491,
R. 497, R. 499).⁴ On June 22, 2018, Plaintiffs filed an omnibus brief in opposition to the

¹ The motion to dismiss identifies the “Distributors” as AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation. (R. 491, PageID# 7455).

² The motion to dismiss identifies the “Pharmacies” as Walmart Inc., Rite Aid Corp., Walgreens Boots Alliance, Inc., and CVS Health Corp. (R. 497, PageID# 7581).

³ The motion to dismiss identifies the “Manufacturers” as Purdue Pharma LP, Purdue Pharma Inc., and The Purdue Frederick Company Inc. (“Purdue”); Allergan Finance, LLC f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc. (“Allergan/Actavis”); Watson Laboratories, Inc., Actavis Pharma, Inc., Actavis LLC, Teva Pharmaceuticals, USA, Inc., and Cephalon, Inc. (“Teva”); Johnson & Johnson (“J&J”); Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica, Inc. (“Janssen”); Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. (“Endo”); Insys Therapeutics, Inc. (“Insys”); and Mallinckrodt LLC (“Mallinckrodt”). (R. 499, PageID# 7632).

⁴ On May 18, 2018, Plaintiffs filed their Second Amended Complaint (R. 477), which included impermissible amendments. After the motions to dismiss were filed, Plaintiffs filed two “corrected” Second Amended Complaints on May 29, 2018—a redacted version (R. 513) and a sealed version. (R. 514). In order to maintain the integrity of the paragraph numbering from the document initially filed on May 18, 2018, the Special Master advised the parties that the

motions. (R. 654). On July 13, 2018, Defendants filed their reply briefs. (R. 742, 744, 746). This report and recommendation addresses all three motions.

I. Fed. R. Civ P. 12(b)(6) Standard

When ruling upon a motion to dismiss filed under Fed. R. Civ. P. 12(b)(6), a court must accept as true all the factual allegations contained in the complaint. *See Erickson v. Pardus*, 551 U.S. 89, 93-94 (2007); *accord Streater v. Cox*, 336 Fed. App'x 470, 474 (6th Cir. 2009).

Nonetheless, a court need not accept conclusions of law as true. Under Fed. R. Civ. P. 8(a)(2), a pleading must contain a “short and plain statement of the claim showing that the pleader is entitled to relief.”

As the Court held in [*Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 127 S. Ct. 1955, 167 L. Ed. 2d 929, the pleading standard Rule 8 announces does not require “detailed factual allegations,” but it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation. *Id.*, at 555, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (citing *Papasan v. Allain*, 478 U.S. 265, 286, 106 S. Ct. 2932, 92 L. Ed. 2d 209 (1986)). A pleading that offers “labels and conclusions” or “a formulaic recitation of the elements of a cause of action will not do.” 550 U.S., at 555, 127 S. Ct. 1955, 167 L. Ed. 2d 929. Nor does a complaint suffice if it tenders “naked assertion[s]” devoid of “further factual enhancement.” *Id.*, at 557, 127 S. Ct. 1955, 167 L. Ed. 2d 929.

To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to “state a claim to relief that is plausible on its face.” *Id.*, at 570, 127 S.Ct. 1955. A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. *Id.*, at 556, 127 S.Ct. 1955. The plausibility standard is not akin to a “probability requirement,” but it asks for more than a sheer possibility that a defendant has acted unlawfully. *Ibid.* Where a complaint pleads facts that are “merely consistent with” a defendant's liability, it “stops short of the line between possibility and plausibility of ‘entitlement to relief.’” *Id.*, at

subsequent “corrected” filings not delete the impermissible amendments, but rather use strike-through font to denote those portions that were no longer operative. Although the parties’ briefs cite to R. 477, the court cites to R. 514 as it is the operative second amended complaint. For the sake of brevity, any reference to the “complaint” hereafter refers to R. 514. Public users unable to access the sealed version may refer to R. 513, where the paragraph numbers should parallel the citations to R. 514.

557, 127 S.Ct. 1955 (brackets omitted).

Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. 544).

A court “may dismiss a complaint for failure to state a claim ‘only if it is clear that no relief could be granted under any set of facts that could be proved consistent with the allegations.’” *Trollinger v. Tyson Foods, Inc.*, 370 F.3d 602, 615 (6th Cir. 2004) (quoting *Swierzkiewickz v. Sorema N.A.*, 534 U.S. 506, 514 (2002); *Hishon v. King & Spalding*, 467 U.S. 69, 73 (1984)).

II. Factual Allegations of the Complaint⁵

A. Increase in Opioid Use/Abuse and Overdose Deaths

The complaint alleges that the Manufacturers and Distributors of opioids began in the late 1990s to expand the use of opioids by developing a “deliberate marketing strategy” coupled with “deliberate efforts to evade restrictions on opioid distribution.” (R. 514 at ¶¶3-4). Plaintiffs allege that annual deaths from opioid overdoses increased sharply from 8,000 in 1999 to 20,000 in 2009 and up to 33,000 in 2015. *Id.* at ¶4. From 1999 through 2016, it is alleged that 350,000 individuals died from an opioid overdose. *Id.* at ¶5. More than 200,000 of those deadly overdoses involved prescription opioids. *Id.* For others who overdosed from non-prescription opioids, such as heroin, it is estimated that 80 percent of people who began abusing heroin in the past decade started with prescription opioids. *Id.* at ¶6. By 2014, nearly 2 million Americans were addicted to prescription opioids with another 600,000 addicted to heroin. (R. 514 at ¶16).

⁵ This report and recommendation provides only a brief overview of the voluminous factual allegations in the over 300 page complaint.

B. Allegations of an Intentional Campaign to Increase Opioid Use

Plaintiffs allege that the Manufacturers⁶ initiated a massive marketing campaign based on false and misleading information to cause a dramatic increase in opioid prescriptions. (R. 514 at ¶10). Despite knowing the highly addictive properties of opioids, the Manufacturers sought to dramatically increase sales by means of publications, websites, and educational programs, resulting in a fourfold increase in opioid sales since 1999 and \$9.6 billion in opioid sales in 2015 alone. *Id.* at ¶¶11-13. Plaintiffs allege the Manufacturers engaged in a series of marketing techniques that knowingly misrepresented both the risks and benefits of opioids for chronic pain treatment in order to “reverse the long-settled understanding of the relative risks and benefits of opioids.” (R. 514 at ¶¶174-175).

1. Nine Categories of Misrepresentations

Plaintiffs allege the Manufacturers employed the following “nine categories of misrepresentations” concerning opioid treatment: (1) the risk of addiction from chronic opioid therapy is low; (2) such risk can be easily identified and managed; (3) signs of addiction are “pseudoaddiction,” requiring more opioids; (4) withdrawal can be avoided by tapering; (5) dosage can be increased without additional risks; (6) long-term opioid use improves functioning; (7) alternative forms of pain relief are riskier; (8) OxyContin provides twelve hours of pain relief; and, (9) new formulas of certain opioids successfully deter abuse. (R. 514 at ¶177).

Plaintiffs assert that all the above are false; that the Manufacturers knew them to be false; and, nonetheless, “set out to convince physicians, patients, and the public at large of the truth of each

⁶ Plaintiffs’ use of the term “Marketing Defendants” includes defendants that have “manufactured and sold” prescription opioids (R. 514 at ¶63), while those same defendants identify themselves as “Manufacturer Defendants” in their motion to dismiss. (R. 499). For the sake of consistency, the court refers to this category of defendants simply as “Manufacturers.”

of these propositions in order to expand the market for their opioids.” *Id.* at ¶178. The complaint proceeds to allege that each of the Manufacturers perpetuated the notion that the risk of addiction from opioid use is low. *Id.* at ¶¶180-232. The complaint also alleges how some of the other eight propositions were perpetuated.⁷ *Id.* at ¶¶233-351.

2. Use of Front Groups, Key Opinion Leaders, and Continuing Medical Education Courses to Spread False and Misleading Information

Plaintiffs further allege that Manufacturers funded and controlled advocacy groups, which Plaintiffs label as “front groups,” that distributed patient education materials and treatment guidelines that overstated the benefits of opioids for chronic pain treatment while understating the risks of addiction. (R. 514 at ¶¶350-354). The front groups were used to create the façade of “neutral and credible third parties” to influence opioid prescribing practices. *Id.* These front groups included both professional societies as well as patient advocacy organizations and received millions of dollars from the Manufacturers. *Id.* at ¶353. Plaintiffs further allege that individual executives, board members, and staff members of these front groups received substantial payments from the Manufacturers, many of whom were physicians on the Manufacturers’ payroll, as consultants or speakers at medical events. *Id.* at ¶¶354, 363. These front groups minimized addiction risks while promoting opioid use for chronic pain, criticized existing CDC guidelines for opioid prescribing, and lobbied against existing laws that curbed opioid use. *Id.* at 355. The Manufacturers allegedly guided, reviewed, and approved false and misleading statements issued by the front groups. *Id.* at ¶356.

Plaintiffs identify numerous organizations that allegedly received funding from

⁷ The Plaintiffs acknowledge that “not every Marketing Defendant” propagated each of the nine misrepresentations, but asserts that liability is not predicated upon every Manufacturer perpetuating all nine misrepresentations. (R. 514 at ¶179).

Manufacturers and served as front groups to distribute tens of thousands of pamphlets and other materials containing misrepresentations regarding opioids. Those entities included: American Pain Foundation (APF), an off-shoot of APF, the National Initiative on Pain Control (NIPC), American Academy of Pain Medicine (AAPM), American Pain Society, Alliance for Patient Access (APA), the U.S. Pain Foundation, and the American Geriatrics Society. (R. 514 at ¶¶357-395). Plaintiffs also allege that the Federation of State Medical Boards (FSMB), a trade organization representing various state medical boards, received grants from Manufacturers for specific opioid and pain management programs. *Id.* at ¶¶377-382. Beginning in 1998, the FSMB began “developing treatment guidelines for the use of opioids for the treatment of pain,” that “was produced ‘in collaboration with pharmaceutical companies.’” *Id.* at ¶379. It is alleged that the 1998 Guidelines, as well as a subsequent FSMB publication entitled *Responsible Opioid Prescribing*, “convey[ed] the alarming message that ‘under-treatment of pain’ would result in official discipline, but no discipline would result if opioids were prescribed as part of an ongoing patient relationship and prescription decisions were documented.” (R. 514 at ¶¶381-382).

Plaintiffs also allege that the Manufacturers “paid and cultivated a select circle of doctors who were chosen and sponsored” for their pro-opioid messages in order “to create the grave misperception science and legitimate medical professionals favored the wider and broader use of opioids.” (R. 514 at ¶396). Plaintiffs label these doctors “key opinion leaders” (KOLs). *Id.* at ¶¶176, 398. They were used “to present the appearance that unbiased and reliable medical research supporting the broad use of opioid therapy for chronic pain had been conducted and was being reported on by independent medical professionals.” *Id.* at ¶397. The publications of these physicians were funded by the Manufacturers as they supported the position that opioid treatment for chronic pain was appropriate, all while knowing these statements were false and

misleading. *Id.* at ¶¶401-403. According to the complaint, one of the KOLs later acknowledged in an interview that his earlier statements were “pseudoscience,” the primary goal of which was to destigmatize opioids. *Id.* at ¶¶410-11.

The Manufacturers are alleged to have “created a body of false, misleading, and unsupported medical and popular literature about opioids that (a) understated the risks and overstated the benefits of long-term use; (b) appeared to be the result of independent, objective research; and (c) was likely to shape the perceptions of prescribers, patients, and payors.” (R. 514 at ¶446). Plaintiffs allege the literature originated from the Manufacturers’ marketing departments and had no scientific research basis. *Id.* at ¶¶448-451. The Manufacturers “aggressively distributed their false message ... through thousands of Continuing Medical Education Courses,” (CMEs), that physicians attended to maintain their licenses. (R. 514 at ¶¶429-432). These CMEs allegedly “inflate the benefits of opioids, and frequently omit or downplay their risks and adverse effects,” causing physicians that listened to these CMEs to be misled. *Id.* at ¶¶433, 440-41.

3. Branded and Unbranded Advertising and Marketing

Plaintiffs allege that the Manufacturers collectively spent more than \$14 million on medical journal advertising of opioids in 2011, which included \$8.3 million by Purdue, \$4.9 million by Janssen, and \$1.1 million by Endo. (R. 514 at ¶442). These included journals targeting specialists, such as the *Journal of Pain and Clinical Journal of Pain*, as well as journals with a wider medical audience, such as the *Journal of the American Medical Association*. *Id.* It is further alleged that the Manufacturers promoted opioids through “unbranded advertising” that, in contrast to a “branded” advertisement, does not require the advertiser to include risks, possible side effects and contraindications. *Id.* at ¶444. Such advertising was directed at physicians and

consumers, as studies have shown that physicians are significantly more likely to prescribe a drug if a patient asks for it. *Id.* at ¶¶443-44. As an example one website contained testimonials from alleged pain advocates, who were paid significant sums by Defendant Purdue. *Id.* at ¶445.

It is further alleged that the Manufacturers' sales representatives met with "hundreds of thousands" of doctors "to disseminate their misrepresentations in targeted, one-on-one settings that allowed them to promote their opioids and to allay individual prescribers' concerns about prescribing opioids for chronic pain." *Id.* at ¶¶452-455. The Manufacturers, in 2014 alone, spent "\$166 million on detailing branded opioids to doctors. This amount is twice as much as the Manufacturers spent on detailing in 2000. The amount includes \$108 million spent by Purdue, \$34 million by Janssen, \$13 million by Teva, and \$10 million by Endo." *Id.* at ¶¶455-461.

C. Distribution and Sales Allegations

Since 1999, the onset of the Manufacturers' alleged marketing actions, the amount of prescription opioids in the United States nearly quadrupled. (R. 514 at ¶12). Plaintiffs maintain that all Defendants were required to register as either manufacturers or distributors pursuant to 21 U.S.C. § 823 and 21 C.F.R. §§ 1301.11, 1301.74. (R. 514 at ¶¶500-504). Plaintiffs allege the Defendants have a duty "to report suspicious orders and further to not ship those orders unless due diligence disproves those suspicions." *Id.* at ¶¶501-505. Plaintiffs allege these duties stem from multiple sources including state law, common law, an assumed duty, and as registrants with the Drug Enforcement Agency (DEA) as manufacturers and/or distributors of Schedule II controlled substances. *Id.*

Plaintiffs assert that the Controlled Substances Act (CSA) requires both the

Manufacturers and the Distributors⁸ of Schedule II substances, such as opioids, to limit sales within a quota set by the DEA; register to manufacture or distribute opioids; maintain effective controls against diversion of the controlled substances that they manufacture or distribute; and to design and operate a system to identify suspicious orders of controlled substances, halt such unlawful sales, and report them to the DEA. *Id.* at ¶507. Plaintiffs allege Defendants failed to control the supply chain, prevent diversion, report suspicious orders, and halt shipments. *Id.* at ¶¶14, 518.

Plaintiffs allege Defendants worked together to increase the supply of opioids and fraudulently increased the quotas that governed the manufacture and distribution of prescription opioids. (R. 514 at ¶¶526-528). It is alleged that the Manufacturers engaged in the practice of paying rebates and/or “chargebacks” to the Distributors for sales of prescription opioids to boost sales and refine their marketing efforts. *Id.* at ¶529. Defendants worked together through trade or other organizations, such as the Pain Care Forum (PCF) or the Healthcare Distribution Alliance (HDA) to increase opioid sales. *Id.* at ¶531. The PCF, which included the previously described front groups, Manufacturers and Distributors, spent \$140 million to lobby state and national legislatures on an array of issues, including opioids. *Id.* at ¶¶533-535.

Furthermore, Plaintiffs allege the HDA created a private network where representatives of the Manufacturers and Distributors could form relationships and create alliances between them and hold strategic business discussions between high-level executives. *Id.* at ¶¶535-540.

⁸ In the complaint, the Plaintiffs also classify the national retail pharmacy defendants as “Distributor Defendants.” (R. 514 at ¶¶107, 111-112, 124-128). These defendants, however, moved separately to dismiss the complaint and, in the Analysis section, the court differentiates between these two categories of defendants by referring to them either as “Distributors” or “Pharmacies.” For the purposes of this section only, the Plaintiffs’ references to the Distributor defendants in the complaint may encompass the Pharmacies.

Thus, Plaintiffs allege that the Manufacturers and Distributors were “not two separate groups operating in isolation or two groups forced to work together in a closed system,” but rather “operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids.” *Id.* at ¶¶543-46. It is alleged the Defendants worked together to ensure that the Aggregate Production Quotas, Individual Quotas and Procurement Quotas allowed by the DEA remained artificially high to ensure that suspicious orders were not reported to the DEA thereby giving the DEA no basis to refuse to increase production quotas due to diversion. *Id.* at ¶¶550-552. Defendants, it is alleged, were “on notice” of the problems of abuse and diversion caused “inescapably from the fact that they flooded communities with opioids in quantities that they knew or should have known exceeded any legitimate market for opioids-even the wider market for chronic pain.” *Id.* at ¶557.

Further, Defendants were “in possession of national, regional, state, and local prescriber- and patient-level data that allowed them to track prescribing patterns over time.” *Id.* at ¶¶558-563. It is also alleged that “Defendants refused to identify, investigate and report suspicious orders to the DEA when they became aware of the same despite their actual knowledge of drug diversion rings.” *Id.* at ¶566. Plaintiffs allege Defendants also failed to report prolific prescribers, but instead focused their sales efforts on them to even further increase their prescribing. *Id.* at ¶¶569-578.

Plaintiffs also allege that several Distributors and Manufacturers have either admitted, been fined for, or been charged with failing to report suspicious orders. (R. 514 at ¶¶580-593, 595). The Defendants, through their trade associations, have acknowledged that “HDMA⁹ and

⁹ HDMA is the Healthcare Distribution Management Association, the predecessor of HDA. (R. 514 at ¶522).

NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society.” *Id.* at ¶599. They further have stated in court filings that “Distributors take seriously their *duty* to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that is available to them in the ordering process.” *Id.* (emphasis added).

It is alleged that the Manufacturers marketed their products and disseminated their misrepresentations in the state of Ohio, and their nationwide “policies, plans, and procedures that were the same in Summit County as they were across the country.” (R. 514 at ¶¶671-672). Sales representatives from each of the Manufacturers visited prescribers in Summit County, which frequently coincided with payments to prescribers for “promotional speaking,” “food and beverage,” “consulting,” “travel and lodging,” “honoraria,” and “education.” *Id.* at ¶673. Summit County had an opioid prescription rate exceeding its population from 2008 to 2011—a rate that has remained higher than the national average.¹⁰ *Id.* at ¶674.

III. Analysis

A. Counts One and Two: Federal RICO Claims

In Count One of the complaint, Plaintiffs allege a civil violation of the Racketeer Influenced and Corrupt Organizations (RICO) Act § 1961 *et seq.* based on a marketing enterprise theory against the Manufactures, specifically Defendants Purdue, Cephalon, Janssen, Endo, and Mallinckrodt, whom the Plaintiffs refer to as “Marketing Defendants.” (R. 514, PageID# 11178).

¹⁰ The complaint states that from 2010 to 2016, according to Ohio data, Summit County, whose population is 540,000 residents, averaged 36.4 million doses of opioids dispensed per year, with a high of 39.5 million. (R. 514 at ¶689).

In Count Two, Plaintiffs allege a civil RICO violation based on a supply chain enterprise theory against both the Manufacturers and Distributors, specifically Defendants Purdue, Cephalon, Endo, Mallinckrodt, Actavis, McKesson, Cardinal, and AmerisourceBergen, whom Plaintiffs refer to as “Supply Chain Defendants.” *Id.* at PageID# 11187.

The RICO Act includes a civil-suit provision that permits: “[a]ny person injured in his business or property by reason of” RICO’s substantive provisions to “sue...in any appropriate United States district court and shall recover threefold the damages he sustains and the cost of the suit, including a reasonable attorney’s fee....” 18 U.S.C. § 1964(c). If a defendant “engages in a pattern of racketeering activity in a manner forbidden by these provisions, and the racketeering activities injure the plaintiff in his business or property, the plaintiff has a claim under § 1964(c).” *Sedima, S.P.R.L. v. Imrex Co., Inc.*, 473 U.S. 479, 495 (1985). The Supreme Court has instructed that “the RICO statute provides that its terms are to be ‘liberally construed to effectuate its remedial purposes.’” *Boyle v. United States*, 556 U.S. 938, 944 (2009) (citations omitted); *accord Ray v. Spirit Airlines, Inc.*, 836 F.3d 1340, 1349 (11th Cir. 2016). The Defendants’ motions challenge Plaintiffs’ RICO standing, allege they failed to plead causation and necessary RICO elements, and assert that Plaintiffs’ supply chain enterprise theory attempts to bring a cause of action for violating the CSA for which they maintain there is no private right of action. (R. 491-1, PageID# 7477-7491, 499-1, PageID# 7664-7689).

1. Standing

“RICO’s civil-suit provision imposes two distinct but overlapping limitations on claimants—standing and proximate cause. Standing poses a threshold question involving constitutional, prudential and (as in this case) statutory limitations on who may sue, regardless of the merits of that person's claim.” *Trollinger*, 370 F.3d at 612 (citing *Allen v. Wright*, 468 U.S.

737, 750-51 (1984)). In addition, “[b]ecause Congress modeled this provision on similar language in the antitrust laws (§ 4 of the Clayton Act and § 7 the Sherman Act) and because the antitrust laws have been interpreted to require that a private plaintiff show proximate cause in order to have standing to sue, RICO civil claims also require proximate cause.” *Trollinger*, 370 F.3d at 612 (citing *Holmes v. Sec. Investor Prot. Corp.*, 503 U.S. 258, 267–68 (1992); *Sedima*, 473 U.S. at 496).

The Defendants are correct in asserting that the standing requirements of a civil RICO claim require a plaintiff to allege (1) a direct injury,¹¹ and (2) the injury is to the plaintiff’s “business or property.” (R. 491-1, PageID# 7478-7486; R. 499-1, PageID# 7664). Plaintiffs summarize their alleged injuries into three categories: (1) public expenditures made in direct response to opioid use and trafficking; (2) lost tax revenue resulting from abuse, misuse, and addiction; and (3) losses caused by diminished property values. (R. 514 at ¶¶ 902, 934).

a. Business or Property

There is no dispute that a RICO claim requires injury to “business or property.” *See, e.g., Sedima*, 473 U.S. at 496 (“the plaintiff only has standing [under RICO] if, and can only recover to the extent that, he has been injured in his *business or property* by the conduct constituting the violation”) (emphasis added); *accord Ray*, 836 F.3d at 1349. Plaintiffs do not contest that such a requirement exists, but rather argue that “[t]he harms that the Manufacturer and Distributor

¹¹ The court views the “direct injury” requirement as a consideration in the proximate cause inquiry and, therefore, addresses it below. *In re Neurontin Mktg. & Sales Practice Litig.*, 712 F.3d 21, 36 (1st Cir. 2013) (citing *Holmes*, 503 U.S. at 274 (“our use of the term ‘direct’ should merely be understood as a reference to the proximate-cause enquiry”)); *see also Wallace v. Midwest Fin. & Mortg. Servs., Inc.*, 714 F.3d 414, 419 (6th Cir. 2013) (stating that RICO incorporated “many traditional proximate-cause considerations,” and that “[o]ne such consideration is directness....”).

Defendants caused, which also impact the Plaintiffs' revenue-generating function, are direct injuries to their 'business and property.'" (R. 654, PageID# 15747).

The Supreme Court in *Reiter v. Sonotone Corporation* analyzed the meaning of "business or property" under the Clayton Act and indicated that "monetary injury, standing alone, may be injury in one's 'property.'" 442 U.S. 330, 340 (1979). The *Reiter* court further noted in the most unambiguous terms that "Money, of course, is a form of property." *Id.* at 338; *see also Chattanooga Foundry and Pipe Works v. City of Atlanta*, 203 U.S. 390, 396 (1906) ("[a] person whose property is diminished by a payment of money wrongfully induced is injured in his property."). Plaintiffs have alleged loss of tax revenue and increased public expenditures as damages in both of their RICO claims. (R. 514 at ¶¶902, 934). "[I]njuries in the form of lost tax revenues and increased law enforcement costs...are at bottom, claims for lost money. Such inherently economic losses constitute injury to 'property' within the meaning of [RICO]." *European Community v. RJR Nabisco, Inc.*, 150 F.Supp.2d 456, 492-93 (E.D.N.Y. 2001) (citing *Reiter*). Moreover, courts have determined that a government entities' loss of tax revenue is a "business or property" interest under RICO. *City of New York v. FedEx Ground Package Sys., Inc.*, 91 F. Supp. 3d 512, 524 (S.D.N.Y. 2015); *City of New York v. Gordon*, 1 F. Supp. 3d 94, 113 (S.D.N.Y. 2013) (finding the city's complaint alleging lost tax revenue "easily satisfies [RICO's injury to business or property] element"); *see also City of New York v. Smokes-Spirits.com, Inc.*, 541 F.3d 425, 445 (2d Cir. 2008) ("[L]ost taxes can constitute injury to 'business or property' for purposes of RICO...."), *rev'd on other grounds sub nom., Hemi Group, LLC v. City of New York*, 559 U.S. 1 (2010) (reversing on lack of proximate cause).

In a criminal action, the Supreme Court held that a government's "right to uncollected excise taxes ... is 'property' in its hands. This right is an entitlement to collect money from

petitioners, the possession of which is ‘something of value’....” *Pasquantino v. United States*, 544 U.S. 349, 355–56 (2005) (“Valuable entitlements [to collect excise taxes] are ‘property’ as that term ordinarily is employed”) (citing *Leocal v. Ashcroft*, 543 U.S. 1, 9 (2004) (“When interpreting a statute, we must give words their ordinary or natural meaning” (internal quotation marks omitted); *Black’s Law Dictionary* 1382 (4th ed. 1951) (defining “property” as “extend[ing] to every species of valuable right and interest”))).

As such, Plaintiffs have alleged a facially plausible claim for injury to their property. Defendants, however, assert that a government entity, when suing as a plaintiff, “cannot rely on expenditures alone to establish civil RICO standing, and there is no indication that the County holds a property interest in the law enforcement or health care services that it provides to the public.” *Canyon Cty. v. Syngenta Seeds, Inc.*, 519 F.3d 969, 976, 979 (9th Cir. 2008). (R. 491-1, PageID# 7480-7481; R. 499-1, PageID# 7665-7666)). Defendants, however, have not identified any Supreme Court or Sixth Circuit case directly on point with the facts of this case. Defendants rely almost exclusively on *Canyon County* and argue that RICO precludes the recovery of such government service expenditures. *Id.* This argument, however, is not persuasive on this record.

i. “Business or Property” as Commercial Interests

Canyon County determined that the “business or property language” found in both RICO and in the Clayton Act should be interpreted uniformly. 519 F.3d at 977. The court held to the view that an injury to business or property under the Clayton Act encompasses only “the interests of the [state] as a party to a commercial transaction.” 519 F.3d at 977 (acknowledging, however, that courts have “often, though not invariably, interpreted the two statutory provisions in a like manner.”); *see also Welborn v. Bank of New York Mellon Corp.*, 557 Fed. App’x 383, 387 (5th Cir. 2014) (“When a government sues under the civil RICO statute, the ‘business or

property’ element requires that the injury ‘refer to commercial interests or enterprises.’”). The Defendants, however, do not cite any Supreme Court or Sixth Circuit authority explicitly stating that a civil RICO action by a governmental entity is limited to property interests that stem from a commercial transaction or commercial interests.

Indeed, the import of the phrase “business or property” in the Clayton Act context has been construed at one time to be limited to “commercial interests.” *See, e.g., Hawaii v. Standard Oil Co. of Cal.*, 405 U.S. 251, 264 (1972) (“[T]he words ‘business or property,’ ... refer to commercial interests or enterprises” and a state may not seek damages for other injuries under the Clayton Act). The language in the *Hawaii* decision was greatly softened by *Reiter*, which also considered the meaning of the phrase “business or property” in the Clayton Act. The *Reiter* Court explained that the *Hawaii* Court’s reference to “the phrase ‘commercial interests or enterprises,’ read [i]n context, in no sense suggests that only injuries to a business entity are within the ambit of [the Clayton Act].” *Reiter*, 442 U.S. at 339 (finding that Congress’ use of the disjunctive in the phrase “business or property” indicates that “‘business’ was not intended to modify ‘property,’ nor was ‘property’ intended to modify ‘business.’”) ¹² The Seventh Circuit Court of Appeals has acknowledged the *Hawaii* decision’s interpretation of the “business and property” phrase under the Clayton Act as referring only to commercial interests and competitive injuries, but held that “this is not the case under RICO.” *Illinois Dep’t of Revenue v. Phillips*, 771

¹² The *Canyon County* decision appears to endorse a restrictive reading of *Hawaii* expressly rejected by *Reiter*. “[T]he language of an opinion is not always to be parsed as though we were dealing with language of a statute.” 442 U.S. at 341-342 (explaining that a “central premise” in *Hawaii* was a “concern over duplicative recoveries” and noting that the state of Hawaii was essentially trying to recover injuries to the business or property of consumers who could recover their own damage).

F.2d 312, 314 (7th Cir. 1985). Other Circuit decisions also cautioned against reflexively applying the Clayton Act’s antitrust principles to RICO. *See, e.g., Schacht v. Brown*, 711 F.2d 1343, 1357-58 (7th Cir. 1983), *cert. denied sub nom. Arthur Andersen & Co., v. Schacht*, 464 U.S. 1002 (1983); *Bennett v. Berg*, 685 F.2d 1053, 1059 (8th Cir. 1982) (“In a RICO context, there are few countervailing reasons to lessen the impact of RICO remedies by imputing the limitations on standing which apply to antitrust law.”). The *Schacht* decision noted that “RICO was broadly aimed at ‘striking ... a mortal blow against the property interests of organized crime,’ and, therefore, it was “reluctant to undermine that broad mission of RICO by engrafting onto its civil provisions a competitive injury requirement.” 711 F.2d at 1358.

ii. Municipal Cost Recovery Rule

Canyon County also applied the municipal cost recovery rule, a tort doctrine developed under state common law, as a basis for concluding the public expenditures alone were insufficient to create RICO standing. 519 F.3d at 974, 979-980. “The ‘municipal cost recovery rule,’ also called the ‘free public services doctrine,’ is a common-law rule which provides that, absent specific statutory authorization or damage to government-owned property, a county cannot recover the costs of carrying out public services from a *tortfeasor* whose conduct caused the need for the services.” 32 A.L.R.6th 261 (Originally published in 2008) (emphasis added). Although the Ninth Circuit acknowledged that “we are not dealing with state common law, but with a statutory cause of action created by Congress [RICO],” the court applied the common law tort doctrine. *Id.* at 980. Furthermore, relying on a prior Ninth Circuit decision—*Diaz v. Gates*, 420 F.3d 897, 900 (9th Cir. 2005)—*Canyon County* found that “[f]inancial loss alone, however, is insufficient” to establish an injury to business or property under RICO “[w]ithout a harm to a specific business or property interest,” and that said inquiry is “typically determined by

reference to state law.” 519 F.3d at 975.

The Sixth Circuit, however, has expressed a different view, acknowledging that “some role” may exist for state law with respect to the question of “where to set the ‘business or property’ threshold” in RICO cases, but emphasizing that this question “depends on federal statutory purpose, and that purpose is likely to support a definition that is uniform throughout the country.” *Jackson v. Sedgwick Claims Mgmt. Servs., Inc.*, 731 F.3d 556, 565 (6th Cir. 2013) (quoting *DeMauro v. DeMauro*, 115 F.3d 94, 96–97 (1st Cir.1997)).¹³ The *Canyon County* court opted to apply the state law doctrine barring recovery of municipal costs based on the notion that had “Congress meant to disrupt settled expectations and alter the legislatively-chosen system of funding local government services[,]” and allow treble recovery “under RICO for injuries arising from [the] provision of governmental services[] ...we believe that Congress would have been more explicit.” 519 F.3d at 980.

The Sixth Circuit, in *Jackson*, however has stated:

Concerns about the scope of RICO are not new. Courts have long recognized that RICO has evolved “into something quite different from the original conception of its enactors,” who sought to “supplement old remedies and develop new methods for fighting crime.” Nonetheless, the unexpected scope of RICO can largely be attributed to the terms of the statute itself. Congress chose “self-consciously expansive language” when it adopted RICO, defined the “predicate acts” necessary to establish a pattern of racketeering activity broadly, and directed courts to give the statute a liberal construction, Organized Crime Control Act of 1970. As a consequence, courts have frequently rejected arguments that RICO should be given constructions that prevent it from reaching conduct that Congress may not have intended it to reach. “[T]he fact that RICO has been applied in situations not expressly anticipated by Congress does not demonstrate ambiguity. It demonstrates breadth.”

* * *

¹³ See also *Miller v. York Risk Servs. Grp.*, 2013 WL 6442764, at *3 (D. Ariz. Dec. 9, 2013) (distinguishing between the Sixth Circuit’s federal statutory purpose inquiry and the Ninth Circuit’s state-law based approach with respect to determining whether there has been a RICO injury to business or property), *adopted*, 2013 WL 11739992 (D. Ariz. Dec. 19, 2013).

Another limitation in § 1964(c) that has its origins in the antitrust laws is the requirement that a plaintiff be “injured in his business or property” in order to bring a civil action. While the Supreme Court has yet to definitively interpret this phrase as it appears in § 1964(c), it has construed it in the context of the antitrust laws. In *Reiter v. Sonotone Corp.*, ... the Court held that “consumers who pay a higher price for goods purchased for personal use as a result of antitrust violations sustain an injury in their ‘business or property’” under § 4. In so doing, it rejected the respondents’ argument that “the phrase ‘business or property’ means ‘business activity or property related to one’s business.’” While conceding the breadth of its ruling that “monetary injury, standing alone, may be injury in one’s ‘property,’” the Court pointed out that “[t]he phrase ‘business or property’ also retains restrictive significance.

Jackson, 731 F.3d at 563-564 (internal citations omitted).

In addition, the court finds instructive other decisions addressing the scope of the municipal cost recovery rule and declining to find that it creates an absolute shield for chronic wrongdoers engaged in a pattern of conduct that creates great public expense. For example, courts have found an exception when the government’s costs are the product of a public nuisance. The Ohio Supreme Court was not persuaded that the municipal cost recovery rule barred Cincinnati’s recovery of expenses for police, emergency, health, corrections, prosecution and other related public services, in an action brought against handgun manufacturers, trade associations, and handgun distributors—alleging tort claims of negligence, product liability, and public nuisance. *Cincinnati v. Beretta U.S.A. Corp.*, 768 N.E.2d 1136 (Ohio 2002). The Ohio Supreme Court stated:

Although a municipality cannot reasonably expect to recover the costs of city services whenever a tortfeasor causes harm to the public, it should be allowed to argue that it may recover such damages in this type of case. Unlike the train derailment that occurred in the *Flagstaff*[¹⁴] case, which was a single, discrete

¹⁴ *Canyon County* relied upon *City of Flagstaff v. Atchison, Topeka & Santa Fe Ry. Co.*, 719 F.2d 322, 324 (9th Cir. 1983). The *Flagstaff* court applied the municipal cost recovery rule, but noted that it does not stand for the proposition that “a governmental entity may never recover the cost of its services. Recovery is permitted where it is authorized by statute or regulation ... or

incident requiring a single emergency response, the misconduct alleged in this case is ongoing and persistent. The continuing nature of the misconduct may justify the recoupment of such governmental costs. Therefore, if appellant can prove all the elements of the alleged torts, it should be able to recover the damages flowing from appellees' misconduct. Moreover, even the *Flagstaff* court recognized that recovery by a governmental entity is allowed "where the acts of a private party create a public nuisance which the government seeks to abate." *Flagstaff*, 719 F.2d at 324. We therefore reject the court of appeals' holding that appellant cannot recover its governmental costs.

Id. at 1149-50.

Similarly, in *City of Boston v. Smith & Wesson Corp.*, 2000 WL 1473568 (Mass. Super. Ct. 2000), the court held that said rule did not bar the city's claim to recover law enforcement and emergency services costs against the defendants—firearms manufacturers, distributors, sellers, and firearms industry trade associations. The court distinguished other decisions applying the doctrine, noting as follows:

What each of these cases has in common is that the acts causing the damage were of the sort the municipality reasonably could expect might occur, and each of the results was a discrete emergency. Fires, fuel spills and ruptured gas mains are all frequent happenings which, while every effort is made to prevent them, can be expected to occur. Train derailments and airplane crashes are more unusual, but not so rare that a municipality can never expect to have to respond to such an emergency. The cases thus stand for the principle that such contingencies are part of the normal and expected costs of municipal existence, and absent legislation providing otherwise are costs to be allocated to the municipality's residents through taxes. In addition, in those cases there is no evidence that the specific defendants had engaged in a repeated course of conduct causing recurring costs to the municipality.

Id. at * 8; *see also James v. Arms Tech., Inc.*, 820 A.2d 27, 48-49 (N.J. App. Div. 2003) ("We do not accept the proposition that [the municipal cost recovery rule's] reasoning should apply in a case such as this, where the City claims a *repeated course of conduct* on defendants' part,

required to effect the intent of federal legislation [or] ... where the acts of a private party create a public nuisance which the government seeks to abate.").

requiring the City to expend substantial governmental funds on a continuous basis.”)(emphasis added);¹⁵ *City of Chicago v. Beretta U.S.A. Corp.*, 821 N.E.2d 1099, 1145 (Ill. 2004) (citing *City of Flagstaff* and noting the public nuisance exception).

When balancing the fact that neither party has identified Supreme Court or Sixth Circuit precedent directly on point, with the Sixth Circuit’s emphasis on federal statutory purpose over state-law based property rules and the jurisprudence confirming that the municipal cost recovery rule does not apply to preclude remedying a repeated course of conduct that allegedly injures a governmental plaintiff, the court is not persuaded that it is applicable to the present set of facts. Moreover, the Sixth Circuit has not indicated that it would concur with the Ninth Circuit’s decision in *Canyon County* as it relates to the application of said rule.¹⁶ The *Cincinnati v. Beretta* and *City of Boston* decisions declined to apply the doctrine to state law tort claims based on the persuasive reasoning that a doctrine that publicly spreads the costs caused by one-time tortfeasors, such as a negligent driver, is inappropriately applied where a defendant engages in a

¹⁵ The court determined the “Municipal Cost Recovery Rule does not apply to cases ... where a municipality seeks to recover damages for the cost of abating a nuisance.” Further, it also indicated that “if the City has a worthy claim, application of the Municipal Cost Recovery Rule would leave the City without a remedy.” *Arms Tech., Inc.*, 359 N.J. Super. at 327-28. The court noted: “[i]f tortious conduct exists, the consequence is that the gun manufacturers are subsidized for their wrongful acts, and the cost of the governmental services must be borne by the taxpayers of the City. This result is fundamentally unfair, given the City’s limited resources and strained ability to provide other essential services to its citizens. Application of the rule also serves as a disincentive; if culpable, the insulated defendants have no reason to obtain liability insurance to cover the cost of their conduct, or to take reasonable measures to eliminate, or at least reduce, the harm resulting from the use of their product.” *Id.* at 328.

¹⁶ The Sixth Circuit’s citations to *Canyon County* in three decisions cannot be construed as endorsing its holding with respect to the “municipal cost recovery rule,” as discussion of that doctrine is entirely absent from those cases. See *Saia v. Flying J. Inc.*, 2017 WL 6398013, at *3 (6th Cir. July 11, 2017), *cert. denied*, 138 S. Ct. 657, 199 L. Ed. 2d 533 (2018), *reh’g denied*, 138 S. Ct. 1182, 200 L. Ed. 2d 328 (2018); *Stooksbury v. Ross*, 528 F. App’x 547, 555 (6th Cir. 2013); *City of Cleveland v. Ameriquest Mort. Sec., Inc.*, 615 F.3d 496, 504, 506 (6th Cir. 2010).

course of repetitive conduct that causes harm of a substantial magnitude and imposes a repeated burden on government services. In addition, the court declines, in this case, to completely transplant that common law tort doctrine to defeat a claim arising under this federal statute. Doing so to defeat well pleaded allegations of an ongoing pattern of intentional racketeering activity is the antithesis of the construction of RICO that Congress designed it to have.¹⁷

b. Personal Injuries

The Defendants also argue that RICO's aforementioned limitation to recovery for an injury to "business or property" eliminates recovery for personal injuries or pecuniary damages flowing from such injuries. (R. 491-1, PageID# 7478-7479; R. 499-1, PageID# 7665) (*citing Doe v. Roe*, 958 F.2d 763, 767 (7th Cir. 1992); *Jackson*, 731 F.3d at 565). The *Jackson* court observed that "those regional circuits that have construed the phrase business or property have uniformly recognized that 'the ordinary meaning of the phrase injured in his business or property excludes

¹⁷ The court also notes that a recent New York supreme court decision addressed whether local governmental entities, who brought suit against opioid manufacturers, were barred from recovering the costs of governmental services by the municipal cost recovery rule. *In re Opioid Litigation*, 2018 WL 3115102 (N.Y. Sup. Ct., Jun. 18, 2018). The court found as follows:

[A] review of the current state of the law revealed no case law supporting the Manufacturers' contention that such rule bars recovery for municipal expenses incurred, not by reason of an accident or an emergency situation necessitating "the normal provision of police, fire and emergency services," but to remedy public harm caused by an intentional, persistent course of deceptive conduct. The Manufacturers' argument that, despite allegations they designed and implemented materially deceptive marketing campaigns to mislead the public and prescribers about the risks and benefits of prescription opioids, the municipal cost recovery rule forecloses the plaintiffs from recovering the costs for services to treat residents suffering from prescription opioid abuse, addiction or overdose, or for the increased costs of programs implemented to stem prescription opioid-related criminal activities, if accepted, would distort the doctrine beyond recognition.

Id. (citations omitted).

personal injuries, including the pecuniary losses therefrom.” 731 F.3d at 564-565 (internal quotation marks omitted); *accord Gucwa v. Lawley*, 731 Fed. App’x 408, 412 (6th Cir. 2018) (“Even though personal injuries may lead to monetary damages, such personal injuries and their associated pecuniary losses—including medical expenses—do not confer relief under § 1964(c).”).

Plaintiffs do not contest that the law precludes recovering such damages, but rather argue that their “damages claims are not for personal injuries, but police and fire services, lost taxes, revenue and funding.” (R. 654, PageID# 15747). They further argue that “[t]he harms that the Manufacturer and Distributor Defendants caused, which also impact the Plaintiffs’ revenue-generating function, are direct injuries to their ‘business and property.’” *Id.* Plaintiffs deny (and the court does not construe) the complaint as seeking to directly recover for the personal injuries sustained by opioid users/addicts. Nevertheless, the law also bars losses flowing from those personal injuries. Whether Plaintiffs’ injuries flow from the personal injuries suffered by their residents is a crucial question in this litigation. Plaintiffs have alleged at least thirteen separate categories of damages with respect to their RICO claims in Counts One and Two. (R. 514, ¶¶902, 934).

The Defendants fail to meaningfully differentiate among the categories, contending they are all derivative of residents’ personal injuries. (R. 491-1, PageID# 7478-7479; R. 499-1, PageID# 7665). Without a full record regarding the source of the various categories of damages, the court declines to paint with such a broad brush. While some of the claimed categories of damages may ultimately not survive if it is revealed through discovery that they fall into an area of prohibited recovery, the court cannot find at this preliminary stage in the proceedings that all thirteen categories are unrecoverable. For example, it is highly debatable whether Plaintiffs’

costs associated with training emergency personnel and first responders flow from an individual resident's personal injuries. (R. 514 at ¶¶902(c), 934(c)). Even further removed from any personal injuries are Plaintiffs' claimed losses associated with lost tax revenue and diminished property values. *Id.* at ¶¶902(k-n), 934(k-m).¹⁸

The Sixth Circuit has instructed that a court “may dismiss a complaint for failure to state a claim ‘only if it is clear that no relief could be granted under any set of facts that could be proved consistent with the allegations.’” *Trollinger*, 370 F.3d at 615 (quoting *Swierzkiewickz*, 534 U.S. at 514). Defendants, as the moving party, have failed to meet their burden of demonstrating that all of Plaintiffs' claimed damages are purely derivative of personal injuries and, therefore, do not constitute an injury to “business or property.” For the foregoing reasons, Defendants' motion to dismiss on these grounds is not well taken.

2. Causation

a. “But for” Cause

The Defendants assert that Plaintiffs have plead no facts establishing “but for” causation. (R. 491-1, PageID# 7516-7517; R. 499-1, PageID# 7666-7672, 7683-7684). First, they maintain that Plaintiffs have not alleged what they characterize as the “first step” in the causal chain—“that specific Ohio prescribers were exposed to the Manufacturers' alleged deceptive marketing” or that but for the Manufacturers' purported failure to monitor and report suspicious orders of prescription opioids to DEA Field Division Offices, Plaintiffs would not have suffered the

¹⁸ The court's recommendation should not be misconstrued as an affirmative finding that none of Plaintiffs' claimed damages are premised upon pecuniary damages flowing from personal injuries. In addition, to the extent that Plaintiffs seek damages for losses of property value in their communities, such claims may, after discovery, be too speculative. *See, e.g. Ameriquest*, 615 F.3d at 505-506. However, in this case, such arguments are more appropriate after the record has been developed.

injuries associated with prescription opioid misuse, abuse, and addiction. *Id.* “But since ‘we presume that general allegations embrace those specific facts ... necessary to support the claim,’ ...causal weaknesses will more often be fodder for a summary-judgment motion under Rule 56 than a motion to dismiss under Rule 12(b)(6).” *Trollinger*, 370 F.3d at 615.¹⁹

Further, the complaint’s allegations set forth a nationwide campaign targeting physicians throughout the United States to change their prescribing practices based on allegedly false statements and misrepresentations. The complaint alleges that the Marketing Defendants carried out this same marketing scheme in Ohio. (R. 514, PageID# 6966-6969, ¶¶671-683) (“The Marketing Defendants all marketed their products and disseminated their misrepresentations in the state of Ohio.”). Plaintiffs also alleged that “sales representatives from each of the Marketing Defendants visited prescribers in Summit County.” *Id.* at ¶673.²⁰ Thus, Defendants’ first assertion is rejected.

Moreover, Defendants contend that Plaintiffs failed to allege that if they had reported suspicious orders to DEA, it would have led to enforcement actions and that would have averted prescription opioid diversion and “related societal harms in Summit County.” (R. 491-1, PageID# 7516; R. 499-1, PageID# 7684). The court disagrees that Plaintiffs are required to

¹⁹ To the extent Defendants argue that Plaintiffs allegations fail to satisfy Rule 9(b)’s pleading requirements, such argument is not persuasive, because courts have recognized that pleadings are sufficient so long as they provide enough detail to put the responding party on notice and enable a response. *See infra* Section III-A-4-a.

²⁰ To the extent Defendants maintain that Plaintiffs were required to name specific prescribers, this court disagrees. Where the alleged scheme is so broad in scope, no meaningful purpose would be served by merely naming a doctor or several doctors to serve as examples of physicians who were misled by Defendants’ marketing scheme. The complaint alleges that Summit County physicians confirmed the existence of the alleged marketing scheme in Summit County. (R. 514 at ¶675). Defendants will certainly have the opportunity to request the identity of these doctors during discovery, and Plaintiffs will need to support their theories with evidence to withstand a motion for summary judgment or persuade the trier of fact.

divine the actions that the DEA would have taken had the Defendants properly reported the suspicious orders as alleged or that Plaintiffs would be required to foresee the alternate series of events had such actions been taken. Contrary to Defendants contention, “but-for” causation is rather easily satisfied by the allegations in the complaint. Reading the complaint’s averments in favor of Plaintiffs, as required when considering a motion to dismiss, they assert but-for Defendants’ allegedly deceptive marketing scheme that changed the way physicians prescribe opioids, coupled with the systemic undermining of quotas and institutional controls as well as the failure to report suspicious orders by both the Marketing and Distributor Defendants, the number of opioids would not have tripled or quadrupled thereby directly giving rise to the opioid epidemic—the costs of which have resulted in Plaintiffs’ alleged injuries. Plaintiffs have sufficiently pled that the Defendants’ alleged actions were the “but for” cause of their injuries as required by 18 U.S.C. § 1964(c) and under *Holmes*, 503 U.S. at 268, and *Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451, 456-61 (2006).

b. Proximate Cause

The Defendants argue that Plaintiffs plead facts that are too attenuated and remote to establish proximate cause. They further contend that the causal chain is broken by: (1) the independent medical judgment of medical professionals who prescribe the opioid products; and (2) third-party criminal acts. (R. 491-1, PageID# 7481-7481; R. 499-1, PageID# 7667-7669). Defendants maintain that Plaintiffs fail to allege a direct relation between their injuries and the conduct of the Defendants. *Id.* Plaintiffs counter that their damages can be properly and efficiently apportioned among the Defendants, that their RICO damages cannot be sought or recovered by *any other party*, and that recovery is necessary to vindicate the purposes underlying RICO and deter future violations. (R. 654, PageID# 15749).

This court cannot say at this early stage of the proceedings that the Plaintiffs’ injuries are so remote as to bar any potential recovery. Plaintiffs, local governments, have been impacted by the opioid epidemic. Their injuries, alleged to be caused by the Defendants’ conspiracy to dramatically increase the usage and supply of opioids for off-label purposes, to some extent, stem from ills associated with opioid use and/or addiction. The connection between their injuries and the Defendants’ alleged racketeering and fraudulent activity is not so attenuated, as their injuries plainly stem from opioid use/abuse and not some possible other source. This court cannot find, absent any discovery, that Plaintiffs’ injuries were incidental to the alleged fraud or the oversupply/diversion of opioids. While Defendants’ alleged actions caused harm to others (*i.e.* those who became addicted to opioids), the ensuing harm to Plaintiffs—the costs associated with responding to and working to stem the opioid epidemic—cannot be deemed incidental. Taking into consideration Plaintiffs’ allegation that as many as 25 percent of patients who receive prescription opioids long-term for chronic pain in a primary care setting become addicted (R. 514 at ¶16), the costs associated with dealing with this surge in addictions cannot be described as incidental but, even if not inevitable in individual cases, it is inescapable in the aggregate.

The Supreme Court has addressed proximate cause under RICO in *Holmes*, 503 U.S. at 258, *Anza*, 547 U.S. at 451, and *Hemi Group LLC*, 559 U.S. at 1. The Manufacturers have asserted that *Anza* is analogous to the case at bar (R. 499-1, PageID# 7665), while the Distributors have asserted that *Hemi* is analogous. (R. 491-1, PageID# 7482-7483). While the court disagrees that any of these decisions are factually analogous to the case at bar, the decisions remain instructive in their application of the *Holmes* factors. The *Holmes* court identified the underlying rationale behind the need for proximate cause as follows: (1) “the less

direct an injury is, the more difficult it becomes to ascertain the amount of a plaintiff's damages attributable to the violation, as distinct from other, independent, factors,” (2) “recognizing claims of the indirectly injured would force courts to adopt complicated rules apportioning damages among plaintiffs removed at different levels of injury from the violative acts, to obviate the risk of multiple recoveries,” and (3) “directly injured victims can generally be counted on to vindicate the law as private attorneys general, without any of the problems attendant upon suits by plaintiffs injured more remotely.” *Holmes*, 503 U.S. at 268.

i. Directness

Relying upon *Anza*, 547 U.S. at 460 and *Jackson*, 731 F.3d at 565, the Defendants, as discussed above, contend that Plaintiffs' injuries are barred because they are derivative of personal injuries suffered by third-party opioid users. (R. 491-1, PageID# 7479-7479; R. 499-1, PageID# 7665). Unsurprisingly, Plaintiffs respond that their damages were directly caused by the Defendants' actions; and, in addition, argue that the *Holmes* factors analysis weighs in favor of finding sufficient proximate cause at this early stage. The Supreme Court has cautioned that “the infinite variety of claims that may arise make it virtually impossible to announce a black-letter rule that will dictate the result in every case” and its use of “the term ‘direct’ should merely be understood as a reference to the proximate-cause enquiry ...” *Holmes*, 503 U.S. at 274, n. 20 (citations omitted).²¹ “The injurious conduct need not be the sole cause of the plaintiffs' injuries,

²¹ Though not a RICO action, the Supreme Court recently addressed proximate cause under the Fair Housing Act (FHA). *Bank of Am. Corp. v. City of Miami, Fla.*, 137 S. Ct. 1296 (2017). Significantly, the Court found that Miami's allegations—that the Defendant banks had discriminated against minorities leading to property tax and municipal spending injuries—arguably fell within the “zone of interests” protected by the FHA. *Id.* at 1303. Further, with respect to proximate cause, despite the fact that Miami's alleged injuries clearly went beyond the “first step” and flowed through individuals who had allegedly been the victims of racially discriminatory lending, the Supreme Court, rather than ordering dismissal, remanded the case for

but there must be ‘some direct relation’ between the conduct and the injury to sustain a claim.”

Ray, 836 F.3d at 1349 (citing *Williams*, 465 F.3d at 1287–88; *Anza*, 547 U.S. at 457).

The first of the *Holmes* factors requires the court to determine how difficult it would be to ascertain which portion of Plaintiffs’ damages resulted from Defendants’ allegedly unlawful conduct versus damages that may be attributable to other factors or to other parties. First, the court notes that injuries in *Holmes* and *Anza*, unlike the injuries asserted herein, were individualized, while the injury asserted herein is rather aggregative.²²

Defendants suggest that there are too many possible intervening causes, identifying the “exercise of independent medical judgment” by physicians who acted as “learned intermediaries,” as well as “intervening third-party criminal acts.” (R. 491-1, PageID# 7483-7484; R. 499-1, PageID# 7669-7670). First, the notion that the physicians cut off the chain of causation ignores pertinent allegations in the complaint. While the complaint alleges that

further analysis of proximate cause. *Id.* at 1306, 1311 (“The lower courts should define, in the first instance, the contours of proximate cause under the FHA and decide how that standard applies to the City’s claims for lost property-tax revenue and increased municipal expenses.”) Several lower courts have also noted that the fact that a plaintiff’s increased costs/damages “runs through a separate injury” to a third party or parties “does not by itself require dismissal on proximate cause grounds.” *Cty. of Cook, Illinois v. Wells Fargo & Co.*, 2018 WL 1469003, at *6 (N.D. Ill. Mar. 26, 2018); *City of Oakland*, 2018 WL 3008538 at *1 (N.D. Cal. June 15, 2018). Nor does the lack of a direct relationship between the plaintiff and defendant defeat nor necessarily frustrate proximate cause. The Sixth Circuit found there was sufficient directness where there is a “link between the scheme and the type of injury [plaintiff] suffered.” *Wallace*, 714 F.3d at 420. “What matters . . . is not whether there is a direct relationship between the plaintiff and defendant, but whether there is a ‘sufficiently direct relationship between the defendant’s wrongful conduct and the plaintiff’s injury’” *In re Volkswagen “Clean Diesel” Mktg., Sales Pracs., & Prod. Liab. Litig.*, 2017 WL 4890594, at *9 (N.D. Cal. Oct. 30, 2017) (citations omitted).

²² In *City of Oakland*, 2018 WL 3008538, at *1, a district court, when confronted with a proximate cause issue in a claim arising under the FHA, observed that “where damages are aggregative, precision is not expected. Invariably some approximation is required,” but noted that “aggregative injury itself does not obviate proximate cause analysis....”

Defendants directly targeted patients with their advertising, the lion's share of the allegations point to a systematic campaign, based on allegedly false statements, that *specifically targeted physicians*. Not only is it alleged that Defendants, through their sales representatives, directly contacted hundreds of thousands of prescribers (R. 514, ¶¶452-455), it is also alleged that Defendants sponsored seminars, influenced medical associations, controlled third-party front groups to maintain the guise of impartiality, and finally directly paid KOLs—all to influence physicians' prescribing decisions and to abolish concern regarding opioid addiction/abuse. (*See generally* R. 514). In other words, the complaint alleges that prescribing physicians were also targets of the misrepresentations. Given these allegations, the court declines to find that the physicians' act of writing prescriptions breaks the causal chain, as a matter of law, when the very purpose of the Defendants' alleged scheme was to achieve exactly that result. The complaint further alleges that the Manufacturers and Distributors conspired to increase opioid sales through trade organizations such as the PCF or HAD; they were in a unique position to recognize the diversion of drugs and did in fact make such a recognition; and they concealed this information despite an obligation to report suspicious orders, all in order to further their supply chain scheme. (R. 514, ¶¶498-593, PageID# 6918-6947). Defendants have no cogent rationale explaining how the prescribing physicians would be an intervening cause with respect to the supply-side allegations.

The court also disagrees that the complaint's RICO claims are rendered deficient by the failure to specifically identify a prescribing physician who relied on Defendants' alleged fraudulent statements. The First Circuit Court of Appeals rejected a similar argument, in *In re Neurontin Litigation*, where the defendants had maintained that "its supposed misrepresentations went to prescribing doctors, and so the causal link to Kaiser [a healthplan provider and insurer]

must have been broken.” 712 F.3d 21, 37 (1st Cir. 2013). Relying on the Supreme Court’s holding in *Bridge*,²³ the circuit court rejected that argument. The court of appeals also rejected the argument that “no physician in this case, or in the Neurontin MDL as a whole, testified that he or she prescribed Neurontin because of defendants’ fraudulent off-label marketing,” an argument that mirrors Defendants’ argument herein. *Id.* at 29. The court reasoned that plaintiffs had presented “other evidence” of causation to the jury, as well as “evidence as to why such individual [physician] testimony was unreliable.”²⁴ *Id.* In addition, the defendants’ “scheme relied on the expectation that physicians would base their prescribing decisions in part on [their] fraudulent marketing.” 712 F.3d at 39.

Further, the court is unconvinced that Defendants’ reliance on *Ind./Ky./Ohio Reg’l*

²³ The Supreme Court in *Bridge v. Phoenix Bond & Indemnity Co.*, 553 U.S. 639 (2008), held unanimously that a civil-RICO plaintiff does *not* need to show that it *detrimentally relied* on the defendant’s alleged misrepresentations. *See also Wallace*, 714 F.3d at 420 (“While reliance is ‘often used to prove ... the element of causation,’ that does not mean it is the only way to do so, nor does that ‘transform reliance itself into an element of the cause of action.’”) (*citing Bridge*).

²⁴ The plaintiffs’ primary evidence came from expert testimony from a health economics professor, who used “aggregate data and statistical approaches to link patterns in promotional spending to patterns in prescribing for the drug.” 712 F.3d at 30. The expert’s regression analysis “found a causal connection between the fraudulent marketing and the quantity of prescriptions written for off-label indications. She also testified as to why Pfizer’s proposed physician-by-physician analysis of causation was not a scientifically valid approach to causation.” *Id.* The expert testified “as to the well-recognized unreliability in the field of healthcare economics of asking doctors individually whether they were influenced by the many methods of off-label marketing. She said that self-reporting from physicians about patterns of practice that may be controversial shows both conscious reluctance and unconscious bias, which lead them to deny being influenced.” *Id.* Although such expert testimony is not before the court, this case cautions against prematurely determining, without a sufficiently developed record, that certain allegations must be present before causation can be determined to have been sufficiently pled. Defendants’ reliance on *City of Chicago v. Purdue Pharma, L.P.*, for the proposition that the complaint must specifically identify doctors is misplaced, as the district court was addressing state law claims and found that the plaintiffs failed to allege sufficient detail about the false claims. 2015 WL 2208423, at *14 (N.D. Ill. May 8, 2015). Thus, the court finds that the absence “self-reports” from physicians in the complaint is not dispositive. In addition, the court finds the rationale of *In re Neurontin* more compelling.

Council of Carpenters Welfare Fund v. Cephalon, Inc. (“Carpenters”) compels a different result. 2014 WL 2115498 (E.D. Pa. May 21, 2014). Defendants focus on the *Carpenters* court’s observation that “physician-prescribers are presumed to have knowledge of a drug label’s contents.” *Id.* at *6 (citing *In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 240 (3d Cir. 2012)). However, the *Carpenters* decision was based on the finding that the allegations in the complaint were general and conclusory, it did not set forth a general rule that a physician’s knowledge of a drug label insulates a drug manufacturer or distributor from liability for fraudulent marketing or unlawful distribution practices. *Id.* at **6-7. Defendants make no meaningful attempt to illustrate that the current complaint is similarly defective, beyond making generalized statements of insufficiency. (R. 499-1, PageID# 7675-7680). Conversely, in *In re Epogen*, 590 F. Supp. 2d 1282, 1290 (C.D. Cal. 2008), a district court held that the plaintiff’s RICO claims were essentially trying to “shoehorn allegations that Defendants have engaged in off-label promotion in violation of the FDCA into [a] RICO [action].” Although the claims therein were dismissed—with leave to amend—the court observed that “[t]he existence of the FDCA does not completely preclude injured parties from asserting claims of fraud or false advertising.” *Id.* at 1290, 1292. In addition, the court observed that: “[Plaintiffs] *may* bring a RICO claim that is truly based on allegations of mail or wire fraud (in the form of deceptive advertising)....To the extent that Plaintiffs allege that Defendants made false statements or deliberately concealed material facts in order to mislead health care professionals and consumers about the safety of EPO, those claims are viable under RICO.” *Id.* at 1290 (emphasis in original).

Second, Defendants’ statement that third party criminal acts break the chain of causation (R. 491-1, PageID# 7517-7519; R. 499-1, PageID# 7669), even if accepted as true, would fail to

break the chain of causation for those damages that were caused by the legal prescription of opioids. The complaint alleges that out of 350,000 fatal overdoses during the relevant time span, more than 200,000 overdoses involved prescribed opioids rather than illicit heroin. (R. 514 at ¶5). It is further alleged that the vast majority of persons who began using heroin in the relevant time period turned to the drug after becoming addicted to prescription opioids.²⁵ (R. 514 at ¶6). Thus, under the facts pled, the criminal acts involving heroin or the illegal use/trade of legal prescriptions do not, as a matter of law upon consideration of a motion to dismiss, break the chain of causation. Even these actions can to some extent, given the allegations, be attributed and foreseeable to Defendants, who allegedly both flooded the market with opioids and created the demand for them.

Construing the allegations of the complaint as true, the court rejects Defendants' arguments and finds the first factor counsels in favor of proximate cause. The complaint contains sufficiently detailed allegations that a quantifiable causal link existed between Defendants' conduct and the damages suffered by Plaintiffs as a result of the opioid epidemic. The "direct causal connection" requirement has been met, as it is not apparent as a matter of law that "intricate, uncertain" inquiries are required to link the Defendants' alleged conduct to Plaintiffs' injuries. *Anza*, 547 U.S. at 460. Hence, the first of the *Holmes* factor weighs in favor of a finding that proximate cause has been sufficiently plead.

ii. Complexity of Apportioning Damages/Repetitive Recovery

The second *Holmes* factor is perhaps the easiest to apply to the allegations in the present

²⁵ The court recognizes that overdoses involving prescribed opioids may also include individuals who were not the prescribed user of the drug. The fact that this category may include both illicit users as well as those who were prescribed the opioids in question does not preclude proximate cause or warrant dismissal at this preliminary stage.

case. Plaintiffs’ brief in opposition expressly states that they are *not* attempting to recover any of the following: (1) personal injuries incurred by individuals “suffering as a result of [opioid] over-prescription, overuse, and addiction,” (2) funds expended by competitors or non-purchasing customers,²⁶ or (3) “monies for health insurance plan members required to pay increased health insurance premiums....” (R. 654, PageID# 15755). The court also does not construe the complaint as seeking to recover these costs. Plaintiffs’ complaint seeks thirteen categories of damages, which can be summarized into three general categories—(1) public expenditures made in direct response to opioid use and trafficking; (2) reduced tax revenue resulting from that abuse, misuse, and addiction; and (3) losses caused by diminished property values—none of these damages are recoverable by those individuals who became addicted to opioids, as personal injuries. (R. 514 at ¶¶902, 934). These individuals cannot recover from Defendants the public expenditures of Plaintiffs, they cannot claim lost county or municipal tax revenue, and they cannot claim the diminished values of Plaintiffs’ property, or the reduced tax income to Plaintiffs. By way of example, if Plaintiffs seek to recover the costs associated with providing police, firefighters or other emergency personnel with Naloxone to block a potentially fatal overdose (*Id.* at ¶902), this cost cannot be claimed by any other entity except Plaintiffs.²⁷

Therefore, the second *Holmes* factor also weighs in favor of a finding that proximate cause has been sufficiently pled.

²⁶ It is not entirely clear whether Plaintiffs are merely differentiating case law with this statement or disclaiming any interest in monies spent by private providers of emergency services. In any event, it does not meaningfully impact the court’s conclusion.

²⁷ If discovery were to reveal that Plaintiffs routinely assessed these costs to the individuals who required them and/or to their insurers, and that Plaintiffs actually recovered such costs, Defendants would in no way be precluded from arguing that no damages were incurred.

iii. Other Injured Parties Vindicating the Law

The third and final *Holmes* factor is an inquiry into whether more directly injured victims can bring suit. Plaintiffs argue that if their suit is barred “few, if any, victims of the RICO conspiracy will be able to ‘vindicate the law as private attorneys general.’” (R. 654, PageID# 15754) (*quoting Holmes*, 503 U.S. at 269-270). Of course, it is too early to determine whether any laws have been violated. Nevertheless, taking the allegations as true, the court agrees with Plaintiffs that no other category of potential plaintiff groups, aside from states and their political subdivisions, can be counted on to vindicate the law in the same manner.²⁸

The court again finds *In re Neurontin* instructive. Although the plaintiff therein was an insurer and not a government entity, the court noted that there was no risk of duplicative recovery because “[n]either the individual physicians, nor the [Drug Information Service] members, nor the [Pharmacy and Therapeutics] Committee members—the parties to whom [defendant] directly made its misrepresentations—ever paid anything toward a Neurontin prescription, so there is no risk of multiple recoveries due to a suit by another of those actors.” 712 F.3d at 37. Defendants have not shown that another party would be able to recover for the specific damages Plaintiffs sustained from Defendants’ alleged enterprise. The third factor also favors a finding that proximate cause has been sufficiently pled.

Based on the application of the *Holmes* factors, the court concludes that the connection between Plaintiffs’ injuries and the Defendants’ alleged scheme—to vastly increase opioid sales by changing physician prescribing practices through fraud coupled with increasing the supply of

²⁸ Defendants have stridently asserted that civil RICO damages are unavailable for personal injuries. (R. 491-1, PageID# 7478-7479; R. 499-1, PageID# 7665). In such case, patients, who were inappropriately prescribed opioids and suffered physical or mental injuries as a result, would be precluded from bringing a RICO claim to recover for their personal injuries.

opioids by failing to report suspicious orders—“is not so indirect, unforeseeable, or illogical that the defendants must prevail as a matter of law.” *Wallace*, 714 F.3d at 422.

3. Existence of an Enterprise

“The [RICO] statute does not specifically define the outer boundaries of the ‘enterprise’ concept but states that the term ‘includes any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity.’” *Boyle*, 556 U.S. at 944 (citing § 1961(4)). The *Boyle* court recognized that the definition of enterprises was “obviously broad” and ensure[d] that the definition has a wide reach. *Id.* Some structure, however informal, was found to be necessary, because: “it is apparent that an association-in-fact enterprise must have at least three structural features: a purpose, relationships among those associated with the enterprise, and longevity sufficient to permit these associates to pursue the enterprise’s purpose.” *Id.*

[A]n association-in-fact enterprise is simply a continuing unit that functions with a common purpose. Such a group need not have a hierarchical structure or a “chain of command”; decisions may be made on an ad hoc basis and by any number of methods—by majority vote, consensus, a show of strength, etc. Members of the group need not have fixed roles; different members may perform different roles at different times. The group need not have a name, regular meetings, dues, established rules and regulations, disciplinary procedures, or induction or initiation ceremonies. While the group must function as a continuing unit and remain in existence long enough to pursue a course of conduct, nothing in RICO exempts an enterprise whose associates engage in spurts of activity punctuated by periods of quiescence.

Id. at 944, 948 (footnotes omitted).

Defendants contend that Plaintiffs have not alleged any facts that could establish the three requisite structural features. (R. 499-1, PageID# 7673-7674, 7685-7686; R. 491-1, PageID# 7490). Specifically, they argue that Plaintiffs have failed to allege that “each defendant had ‘some part in directing the enterprise’s affairs.’” *Id.* (quoting *United States v. Fowler*, 535 F.3d

408, 419 (6th Cir. 2008) (citing *Reves v. Ernst & Young*, 507 U.S. 170, 179 (1993)). Defendants also assert that the complaint fails to allege a “common purpose,” and merely alleges profit-seeking activity by competitors. The court disagrees. First, pursuit of profit is not the exclusive province of legitimate commercial endeavors. Second, Plaintiffs clearly allege a vast scheme that had a fundamental overarching purpose—to materially expand prescription opioid use by altering the medical community’s prescribing practices of opioids through repeated fraudulent statements and misrepresentations. The Defendants allegedly used front groups and KOLs, as well as their own sales representatives, to spread their false and misleading message. If such a conspiracy is established by the facts, a profit motive would not negate a common purpose. While Defendants would characterize the allegations as alleging merely “a pattern of crimes” “independently and without coordination,” (R. 499-1, PageID# 7673), it is alleged that front groups, such as APF, AAPM, and APA, were funded and directed by multiple Defendants to spread their false message under the guise of a neutral third party. (R. 514 at ¶¶357-428).

On the supply side, the Distributors attempt to portray the allegations as establishing no more than “routine business relationships” or “membership in trade organizations.” (R. 491-1, PageID# 7491). Defendants’ contentions turn a blind eye to allegations that allege much more. It is alleged the PCF and the HDA created a private network where representatives of the Manufacturers and Distributors could form relationships and create alliances and hold strategic business discussions between high-level executives. (R. 514 at ¶¶534-553). Plaintiffs further allege that the Manufacturers and Distributors were “not two separate groups operating in isolation or two groups forced to work together in a closed system,” but rather they “operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids.” *Id.* at ¶¶543-546. Though Defendants may have competed over the ever-

mushrooming opioid market, that does not shield them from allegations of racketeering activity in furtherance of a scheme to grow that market.

Defendants assert that their mere participation in trade associations is insufficient to form an enterprise. (R. 744, PageID# 17655; R. 746, PageID# 17711). “In *Boyle*, the [Supreme] Court upheld an instruction that allowed a jury to find an association-in-fact enterprise ‘form[ed] solely for the purpose of carrying out a pattern of racketeering acts’ and instructed that ‘[c]ommon sense suggests that the existence of an association-in-fact is oftentimes more readily proven by what it does, rather than by abstract analysis of its structure.’” *Ouwinga v. Benistar 419 Plan Servs., Inc.*, 694 F.3d 783, 794 (6th Cir. 2012) (citing *Boyle*, 556 U.S. at 942). “[A] pattern of racketeering activity may be sufficient in a particular case to permit a jury to infer the existence of an association-in-fact [enterprise].” *Id.* at 951. It is alleged, for example, that the Manufacturers and Distributors used the HDA to jointly increase production quotas, to stymie efforts that would prevent the diversion of opioids, and to coordinate their refusal to report suspicious orders, including those made by direct competitors. (R. 514 at ¶¶545-552). Defendants do not meaningfully explain how these relationships are insufficient as a matter of law. (R. 746).

An inability to describe the exact inner workings of these associations, without the benefit of discovery, is not dispositive at this stage. At the same time, the allegations in the complaint are significantly more detailed than a mere assertion that because the Defendants were members of a trade association that they must have been part of an illicit enterprise. Again, discovery may yield no fruit in this regard, but Plaintiffs should have an opportunity to prove the substance of their allegations.

Finally, Plaintiffs have alleged longevity sufficient to pursue the enterprise’s purpose—

the 1990s to the present. (R. 514 at ¶¶829, 834).

4. Racketeering Activity

The Defendants argue that Plaintiffs fail to plead any actionable “racketeering activity.” (R. 491-1, PageID# 7486-7490; R. 499-1, PageID# 7674-7678, 7686). “RICO takes aim at ‘racketeering activity,’ which it defines as any act ‘chargeable’ under several generically described state criminal laws, any act ‘indictable’ under numerous specific federal criminal provisions, including mail and wire fraud” *Sedima*, 473 U.S. at 481. Plaintiffs allege Defendants engaged in mail and wire fraud under 18 U.S.C. §§ 1341 and 1343. (R. 514 at ¶¶888-890, 911-916).

a. Marketing Enterprise Claim

“When pleading predicate acts of mail or wire fraud, in order to satisfy the heightened pleading requirements of Rule 9(b), a plaintiff must ‘(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent.’” *Heinrich v. Waiting Angels Adoption Servs., Inc.*, 668 F.3d 393, 404 (6th Cir. 2012) (citing *Frank v. Dana Corp.*, 547 F.3d 564, 570 (6th Cir. 2008)). Nevertheless, a RICO plaintiff is *not* required to plead or prove first-party reliance on an allegedly false statement. *See Bridge*, 553 U.S. at 648. In addition, “courts have relaxed Rule 9(b)'s heightened pleading requirements in cases involving complex fraudulent schemes or those occurring over a lengthy period of time and involving thousands of billing documents.” *In re U.S. Foodservice Inc. Pricing Litig.*, 2009 WL 5064468, at *18 (D. Conn. Dec. 15, 2009) (“dates, times and places need not be pleaded with absolute precision, so long as the allegations sufficiently put the defendant on notice as to the circumstances of the charged misrepresentations.”) (citations omitted); *In re Sumitomo Copper Litig.*, 995 F. Supp.

451, 456 (S.D.N.Y. 1998) (“In complex civil RICO actions involving multiple defendants, therefore, Rule 9(b) does not require that the temporal or geographic particulars of each mailing or wire transmission made in furtherance of the fraudulent scheme be stated with particularity.”).

The Manufacturers assert that the marketing enterprise and supply chain enterprise RICO claims are based entirely on allegations that they fraudulently marketed opioids, but the complaint fails to plead “any such fraudulent marketing anywhere in Summit County as to any Manufacturer Defendant with the particularity required by Rule 9(b).” (R. 499-1, PageID# 7678, 7688). They further aver that the so-called “nine categories of misrepresentations” alleged in the complaint do not satisfy the particularity requirements of Rule 9(b). *Id.* at PageID# 7679. They further contend that Plaintiffs impermissibly rely on the statements of third-parties. *Id.* at PageID# 7681. Plaintiffs point to *Williams v. Duke Energy Intern., Inc.*, wherein the Sixth Circuit Court of Appeals stated:

[T]his court has held that “[i]t is a principle of basic fairness that a plaintiff should have an opportunity to flesh out her claim through evidence unturned in discovery. Rule 9(b) does not require omniscience; rather the Rule requires that the circumstances of the fraud be pled with enough specificity to put defendants on notice as to the nature of the claim.” *Michaels Bldg. Co. v. Ameritrust Co., N.A.*, 848 F.2d 674, 680 (6th Cir. 1988). “Especially in a case in which there has been no discovery, courts have been reluctant to dismiss the action where the facts underlying the claims are within the defendant's control.” *Id.*

681 F.3d 788, 803 (6th Cir. 2012). A recent decision from this district supports that notion and cautions that “Rule 9’s pleading requirement of particularity must be read in harmony with Rule 8’s ‘policy of simplicity in pleading[.]’ [and] ... courts should not be ‘too exacting’ or ‘demand clairvoyance from pleaders’ in determining whether the requirements of Rule 9(b) have been met.” *Ford v. Pa. Higher Educ. Assist. Agency*, 2018 WL 1377858 at *4 (N.D. Ohio Mar. 19, 2018) (Lioi, J.) (citations omitted); *see also In re Sumitomo Copper Litig.*, 995 F. Supp. at 456

(“In cases in which the plaintiff claims that the mails or wires were simply used in furtherance of a master plan to defraud, the communications need not have contained false or misleading information themselves [and] a detailed description of the underlying scheme and the connection therewith of the mail and/or wire communications, is sufficient to satisfy Rule 9(b).”) (*citing Schmuck v. U.S.*, 489 U.S. 705, 715 (1989)).

Plaintiffs have sufficiently alleged that the Manufacturers engaged in an “Opioid Marketing Enterprise.” At a minimum, they have sufficiently alleged that mail and wire communications were a “step in the plot” of the overarching fraudulent scheme.²⁹ It is alleged that the “[t]he pattern of racketeering activity used by the RICO Marketing Defendants ... likely involved thousands of separate instances of the use of the U.S. Mail or interstate wire facilities in furtherance of the unlawful Opioid Marketing Enterprise, including essentially uniform misrepresentations, concealments and material omissions regarding the beneficial uses and non-addictive qualities for the long-term treatment of chronic, non-acute and non-cancer pain...” (R. 514 at ¶¶839, 840-848). As set forth in the summary above, the complaint details nine categories of specific misrepresentations. It further sets out how the so-called misrepresentations were disseminated, including through speakers’ programs, front groups, KOLs, and directly through sales representatives.

²⁹ In *Schmuck*, 489 U.S. at 710-711, the Supreme Court explained that:

The federal mail fraud statute does not purport to reach all frauds, but only those limited instances in which the use of the mails is a part of the execution of the fraud, leaving all other cases to be dealt with by appropriate state law.” To be part of the execution of the fraud, however, the use of the mails need not be an essential element of the scheme. It is sufficient for the mailing to be “incident to an essential part of the scheme,” or “a step in [the] plot.”

(internal citations and footnotes omitted).

Whether these so-called misrepresentations were indeed false or misleading is an issue of fact. Defendants' motion to dismiss demands an untenable level of specificity above and beyond the pleading rules. Plaintiffs cannot be expected to plead the minutiae of their case without the benefit of discovery.³⁰ Further, the court finds compelling the reasoning of a decision from the Southern District of New York:

[I]t is difficult to see any useful purpose in requiring that a RICO complaint specifically allege each mailing in furtherance of a complex commercial scheme, at least where, as here, the complaint alleges that numerous mailings of particular kinds were made in furtherance of the scheme. Once the plaintiff alleges with particularity the circumstances constituting the fraudulent scheme, neither the reputational interests nor the notice function served by Rule 9(b) would be advanced in any material way by insisting that a complaint contain a list of letters or telephone calls.

Spira v. Nick, 876 F. Supp. 553, 559 (S.D.N.Y. 1995) (footnotes omitted). Taking into consideration the clandestine nature of the alleged conspiracy to swell the market for opioids by undermining the medical community's apprehension towards prescribing them, it is unsurprising that Plaintiffs cannot connect each dot in the conspiracy without the benefit of discovery, as the evidence necessary to prove their allegations, if it exists, undoubtedly lies primarily in the hands of Defendants. Given the detailed allegations of the complaint, it cannot reasonably be deemed a fishing expedition.

³⁰ Defendants repeated statement that Plaintiffs have failed to identify even one Summit County prescriber who relied on the misrepresentations is a red herring. Plaintiffs allege that interviews with Summit County doctors have confirmed that Defendants' sales representatives "carried the deceptive messages to local prescribers." (R. 514 at ¶675). Defendants will have ample opportunity to ascertain the identity of these doctors in discovery. The allegation that Ohio is one of the hardest hit states by the opioid epidemic, with 39.5 million opioid doses dispensed in Summit County in 2012 alone for a county-wide population of 540,000, coupled with the allegation that it leads the nation in overdose deaths per capita, when accepted as true, renders hollow any notion that the Defendants' more than a decade long nationwide push to expand prescription opioid use failed to permeate Summit County. *Id.* at ¶¶689, 714-719.

Finally, the Manufacturers' assertion that Plaintiffs are relying on statements made by third parties fails to read the complaint as a whole. (R. 499-1, PageID# 7681-7682). Plaintiffs have alleged that the Manufacturers spent millions of dollars on both advertising as well as direct contact with physicians through sales representatives, through which they spread their alleged misrepresentations concerning the safety and efficacy of opioids; that the Manufacturers created the body of literature to support false assertions; and that so-called third parties were merely front groups or KOLs sponsored and controlled directly by the Manufacturers. (R. 514 at ¶¶442-445, 448-455). Although the veracity of these allegations may be in dispute, they cannot be challenged in a 12(b)(6) motion.

b. Supply Chain Enterprise

i. Mail and Wire Fraud

The Distributors also assert that Plaintiffs have failed to allege with sufficient particularity any predicate acts of mail or wire fraud under RICO. (R. 491-1, PageID# 7486-7487). Without repeating the requirements of mail or wire fraud pleading set forth above, the complaint itself appears to concede that a high level of specificity is lacking, but asserts that “[m]any of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities have been deliberately hidden by Defendants and cannot be alleged without access to Defendants’ books and records. However, Plaintiffs have described the types of, and in some instances, occasions on which the predicate acts of mail and/or wire fraud occurred.” (R. 514 at ¶871). The complaint does broadly aver that the Distributors used the mail and/or the wires to ship the opioids themselves, to seek higher production/procurement quotas, to submit reports to the DEA that contained material omissions and/or misrepresentations, to transmit documents that facilitated the transport of the opioids, to process rebates and chargebacks, to make payments to

trade organizations such as the HDA—all while being aware that many of the orders were suspicious, exceeded any reasonable amount for legitimate purposes, and subject to diversion. *Id.* at ¶¶855-877.

Furthermore, all three of the moving Distributors are alleged to have paid millions of dollars in civil penalties and/or settlement agreements with the United States and/or the state of West Virginia involving similar allegations that they failed to report suspicious orders of controlled substances: in 2016 AmerisourceBergen Drug Corporation settled a lawsuit with West Virginia for \$16 million (R. 514 at ¶585); in 2016 Cardinal Health, Inc. agreed to pay \$44 million to the United States and \$20 million to West Virginia (*Id.* at ¶¶584-585); and, in 2017 McKesson Corporation agreed to pay \$150 million to the United States. (*Id.* at ¶¶581-582). While the court does not construe any of these allegations as admissions by the Distributors, these facts do bolster the plausibility of Plaintiffs’ allegations.

Finally, as stated above, the specific evidence of a conspiracy, if indeed one existed, would lie in the hands of Defendants.

ii. Felonious Manufacture, Importation, Receiving, Concealment, Buying, Selling, or Otherwise Dealing in a Controlled Substance as a Predicate Act

The Defendants also challenge the alleged supply chain enterprise, asserting that Plaintiffs have failed to allege a predicate act under RICO. (R. 491-1, PageID# 7486, 7488-7489; R. 499-1, PageID# 7686-7687). “Section 1961(1) [of the RICO Act] contains an exhaustive list of acts of ‘racketeering,’ commonly referred to as ‘predicate acts.’” *Beck v. Prupis*, 529 U.S. 494, 497 at n. 2 (2000). Under RICO, “racketeering activity” includes “the *felonious* manufacture, importation, receiving, *concealment*, buying, *selling*, or *otherwise dealing* in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substances

Act), punishable under *any law* of the United States.” 18 U.S.C. § 1961(1)(D) (emphasis added). The Manufacturers concede that “certain conduct involving the manufacture and distribution of controlled substances may constitute a predicate act if it is ‘punishable by imprisonment for more than one year.’” (R. 499-1, PageID# 7686). They maintain, however, that the alleged “failure to monitor and report suspicious orders amounts to (at most) a violation of 21 U.S.C. § 842(a)(5)” and is not punishable by more than a year. (R. 499-1, PageID# 7687). Defendants fail to cite any authority that limits Plaintiffs’ allegations to § 842, a position not compelled by the plain language of the code.³¹ (R. 746, PageID# 17717).

Plaintiffs counter that Defendants’ failure to report suspicious orders instead violates § 843, which makes it unlawful to “knowingly or intentionally ... furnish false or fraudulent material information in, or omit any material information from, any application, report, record, or other document required to be made, kept, or filed under this subchapter or subchapter II...” (R. 654, PageID# 15770, *citing* 21 U.S.C. § 843(A)(4)(a)). Such a violation is punishable by up to four years imprisonment. 21 U.S.C. § 843(d)(1). Despite the admission in their motion to dismiss that the felonious dealing in a controlled substance constitutes a predicate act, Defendants assert that a violation of § 843(a)(4)(A) would not qualify as a predicate act because it is not specifically enumerated in § 1961(1)(D).³² (R. 491-1, PageID# 7488; R. 499-1, PageID# 7694-

³¹ § 842 applies to persons who “refuse or negligently fail to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information required under this subchapter or subchapter II...” The complaint alleges intentional conduct that goes well beyond negligence—that Defendants knew about suspicious orders from their own sales representatives and the exacting data they kept but concealed them. (R. 514 at ¶¶554-593).

³² The Distributors cite one non-binding decision in their argument: *In re Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig.*, 590 F. Supp. 2d 1282, 1290 (C.D. Cal. 2008). (R. 491-1, PageID# 7488-7489). That case, however, is inapposite and contains no discussion at all as to whether a violation of § 843(a)(4)(A) may serve as a predicate act under the language of § 1961(1)(D). Further, the plaintiff therein alleged RICO liability solely on the basis of off-label

7695). Without relying on any binding case law to support their argument, Distributors assert that “[v]iolations of Section 843(a)(4) do not fall within that language [of 18 U.S.C. § 1961(1)(D)]” because providing false information or making material omissions does not constitute “buying, selling, or otherwise dealing” in controlled substances. (R. 491-1, PageID# 7488). First, the court is skeptical whether providing false information, as alleged, does not constitute “concealment” or “otherwise dealing in a controlled substance” as Distributors suggest. Second, the court takes note that in making the above assertion, the Distributors completely cut out the provision of § 1961(1)(D) that expressly references “concealment” of a controlled substance and furnishing false information as alleged may constitute concealment. Thus, the plain language of § 1961(1)(D) does not appear to preclude the use of a violation of § 843(a)(4)(A) as a predicate act. The argument that § 843 is not expressly enumerated as a predicate act by § 1961(1)(D) is untenable, as § 1961(1)(D) does not identify any single, specific section of the United States Code that would constitute a predicate act under the subsection. If Defendants’ construction were adopted, the entirety of § 1961(1)(D) would be rendered a nullity.

While Defendants maintain their alleged conduct is more akin to a violation of § 842, the question of whether § 842, § 843, or neither was violated is ultimately an issue of fact that cannot

marketing relying exclusively on mail and wire fraud as racketeering activities. *In re Epogen*, 590 F. Supp. 2d at 1287 (“Plaintiffs allege that Defendants’ unlawful promotion of EPO for unsafe, off-label uses constituted a pattern of racketeering activity, including mail and wire fraud.”). The district court did hold that “[a]llowing Plaintiffs to proceed on a theory that Defendants violated RICO by engaging in off-label promotion, without specific allegations that Defendants made false or misleading statements, would, in effect, permit Plaintiffs to use RICO as a vehicle to enforce the FDCA and the regulations promulgated thereunder.” *Id.* at 1289-1290. Plaintiffs correctly note that “the *In re Epogen* plaintiff did not assert felony predicate acts, claims under the CSA, or the existence of a felony violation of the FDCA.” (R. 654, PageID# 15774). Defendants’ attempt to portray *In re Epogen* as holding that a felony violation of either the FDCA or the CSA can never serve as a RICO predicate act under § 1961(1)(D) is far too broad and distorts the limited scope of the decision.

be resolved on a motion to dismiss. Plaintiffs’ argument—that the Manufacturers and Distributors, by allegedly suppressing or refusing to identify and report suspicious orders effectively engaged in activity tantamount to “concealment” or “otherwise dealing in controlled substances”—is construed as true at this pleading stage. Thus, Plaintiffs have sufficiently pled a predicate act pursuant to section 1961(1)(D) with respect to their supply side RICO theory.

Alternatively, the Manufacturers argue that they “have no duty to monitor, prevent, or report the downstream diversion of prescription opioids at the pharmacy or physician level, where diversion occurs.” (R. 499-1, PageID#7687). They maintain that under the “plain text” of 21 C.F.R. § 1301.74(b), their duty extends only to monitoring and reporting suspicious orders placed with them *by their direct customers* (i.e., pharmaceutical distributors). *Id.* Plaintiffs counter that such an argument reads words into the text of the CSA and its regulations that do not exist. (R. 654, PageID# 15770). 21 C.F.R. § 1301.74(b) states:

The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

The plain text of the regulation is not so limiting, and does not state that a registrant’s obligation to report suspicious orders applies only to orders from its direct customers. Rather, the plain text requires the registrant to report suspicious orders whenever one is “discovered by the registrant.”³³ Further, Defendants cite no case law interpreting the provisions of § 1301.74(b) so

³³ Undoubtedly, a registrant manufacturer would have the most precise information about orders from its direct customers. However, the complaint alleges that the Manufacturers, in concert with the Distributors, collected vast amounts of data that, at least plausibly, led to Defendants’ discovery of suspicious orders by parties other than their direct customers.

narrowly. Plaintiffs also fail to cite any authority interpreting the regulation, save for a DEA enforcement action against Mallinckrodt and Mallinckrodt's ensuing admission that "[a]s a registrant under the CSA, [it] had a responsibility to maintain effective controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders to DEA." (R. 654, PageID# 15770, *citing* R. 514 at ¶520). Nonetheless, the onus is on Defendants as the moving party to demonstrate that Plaintiffs fail to state a claim.

For the forgoing reasons, it is recommended that the court deny the motions to dismiss Counts One and Two.

B. Preemption

The Manufacturers argue that all state law claims are preempted, as they conflict with the FDA's decisions regarding approval and labeling of medications. (R. 499-1, PageID# 7689-93).

1. Claims Involving Marketing of Opioids

The Manufacturers portray the complaint as alleging that they falsely represented opioids as safe and effective for the long-term treatment of chronic non-cancer pain. (R. 499-1, PageID# 76989-7690). They argue the FDA has approved this use, which demonstrates that it found "substantial evidence that the drug will have the effect it purports or is represented to have" and that the opioids in question are safe and effective for treating chronic pain. *Id. citing* 21 U.S.C. § 355(d). They cite cases holding that state law claims are preempted where a claim would require a drug manufacturer to make statements about safety or efficacy that differ from what the FDA required. *Id. (citing Rheinfrank v. Abbott Labs., Inc.*, 680 Fed. App'x 369, 386 (6th Cir. 2017); *In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 779 F.3d 34, 42-43 (1st Cir. 2015); *Utts v. Bristol-Meyers Squibb Co.*, 251 F. Supp. 3d 644, 663-73 (S.D.N.Y. 2017)).

Conversely, Plaintiffs dispute that their claims are based on allegations that Defendants falsely claimed their medications were “safe and effective for the long-term treatment of chronic non-cancer pain.” (R. 654, PageID# 15826). Rather, they insist their allegations revolve around Defendants’ “false and misleading promotion of these drugs.” *Id.* They argue that there is no preemptive conflict between their state law claims and federal law, because the latter did not require the Manufacturers to misleadingly promote their products. (R. 654, PageID# 15826). Plaintiffs assert that they do not seek to stop the Manufacturers from selling opioids, but only to stop their deceptive marketing. *Id.* Plaintiffs cite cases in support of the proposition that, “because drug manufacturers are under no federal obligation to promote their products, courts have consistently refused to find preemption of fraud-based marketing claims involving FDA-approved drugs even where the manufacturer would be precluded from altering its label (as in the case of generic drugs for which the manufacturer is required to maintain a label identical to the branded equivalent.)” *Id.*, PageID# 15827 (*citing Arters v. Sandoz Inc.*, 921 F. Supp. 2d 813, 819-20 (S.D. Ohio 2013) (state law fraud claims based on defendants’ allegedly fraudulent or unreasonably dangerous promotion of generic drug were not preempted); *Priest v. Sandoz, Inc.*, 2016 WL 11162903, at *7 (W.D. Tex. Dec. 29, 2016), *report and recommendation adopted*, 2016 WL 8896188 (W.D. Tex. Jan. 31, 2017) (obligation to refrain from falsely promoting drugs does not make it impossible to comply with federal law regarding labelling); *Beavers-Gabriel v. Medtronic, Inc.*, 2015 WL 143944, at *6 (D. Haw. Jan. 9, 2015) (no impossibility preemption for fraud claims); *Elmore v. Gorsky*, 2012 WL 6569760, at *3 (S.D. Tex. Dec. 17, 2012)).

The cases upon which Defendants rely are all distinguishable. *Rheinfrank* is inapposite because it was argued the defendant should have added a warning label the FDA had twice refused. 680 Fed. App’x at 384-388. In *In re Celexa*, it was argued that the FDA should not have

approved Lexapro, and that defendant should have shared negative efficacy information with the FDA. 779 F.3d at 36-43. Because the FDA had reviewed this information and approved the drug, the state law claim was in conflict with federal law. *Id.* In *Uts*, the plaintiffs' fraud-based claims were preempted, because they alleged a fraud upon the FDA. 251 F. Supp. 3d at 679-680 (*citing Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001) (holding that state law fraud on the FDA claims conflict with federal law and are impliedly preempted)). Herein, the state law claims are not premised upon inappropriate labeling or a fraud upon the FDA, but rather fraudulent marketing in the promotion and sale of their opioids.³⁴

At this current stage of the proceedings, Defendants have not met their burden to show that Plaintiffs' claims are preempted.

2. Claims Involving Off-Label Uses

The Manufacturers also argue that claims related to the inappropriate promotion of opioids for off-label uses are preempted. (R. 499-1, PageID# 7689-7691). Preemption is required, they assert, because the FDA is invested with exclusive authority and a variety of enforcement options to address off-label promotion. *Id.* Moreover, the FDCA does not create a private right of action to enforce its provisions. *Perdue v. Wyeth Pharms., Inc.*, 209 F.Supp.3d 847, 851-52 (E.D.N.C. 2016); *see also McDaniel v. Upsher-Smith Pharms., Inc.*, 229 F.Supp.3d 707, 713 (W.D. Tenn. 2017).

Plaintiffs assert they are not suing to enforce FDCA off-label use rules, but rather contend that Defendants misrepresented the risks associated with off-label opioid use. (R. 514,

³⁴ The Manufacturers' reply characterizes Plaintiffs' brief as conceding that various claims are preempted. (R. 746, PageID# 17706-17707). The court does not construe Plaintiffs' brief as abandoning or conceding any of their state law claims as preempted. But after discovery, the Plaintiffs may narrow their claims and Defendants may renew their arguments upon a full record.

PageID# 6818-6869, ¶¶177-349). They argue that state law claims may proceed on such grounds even where the alleged wrongful conduct might also violate the FDCA. (R. 654, PageID# 15829-15830). Moreover, Plaintiffs assert that state law claims founded on violations of federal law duties are precluded only to the extent that they “exist solely by virtue of” the federal law in question and do not “rely on traditional state tort law.” *Buckman*, 531 U.S. at 352-353. They rely upon cases in which state law claims proceeded on such grounds even where the alleged wrongful conduct might also have violated the FDCA. *Id.*; see also *Loreto v. Procter & Gamble Co.*, 515 Fed. App’x 576, 580 (6th Cir. 2013); *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2d Cir. 2006), *aff’d sub nom. Warner-Lambert Co., LLC v. Kent*, 552 U.S. 440 (2008); *Arters*, 921 F. Supp. 2d at 819-20.

The Sixth Circuit, in *Loreto*, indicated that “plaintiffs may not bring a state-law claim against a defendant when the state-law claim is in substance (even if not in form) a claim for violating the FDCA.” 515 Fed. App’x 576 at 579. The *Loreto* court explained its method for distinguishing between state law claims that seek to enforce the FDCA and those that actually arise under state law; only the former are preempted. *Id.* The *Loreto* court noted,

[T]he conduct on which the claim is premised must be the type of conduct that would traditionally give rise to liability under state law—and that would give rise to liability under state law even if the FDCA had never been enacted. If the defendant’s conduct is not of this type, then the plaintiff is effectively suing for a violation of the FDCA (no matter how the plaintiff labels the claim), and the plaintiff’s claim is thus impliedly preempted under *Buckman*.

Id. The *Loreto* court found no preemption of a claim that a manufacturer’s marketing materials misrepresented the health benefits of vitamin C in its over-the-counter cold remedy, ruling that the claim relied “solely on traditional state tort law predating the FDCA,” even though the conduct also violated the FDCA. *Id.* at 580. In *Arters*, it was alleged that the defendants had

promoted Amiodarone as a routine treatment, rather than as a drug of last resort. 921 F. Supp. 2d at 819-820. The court held that claims arising from off-label promotion did not seek to enforce the FDCA, because plaintiff did not allege that defendants violated their duty on the ground that the promotion was off-label, but rather because it was fraudulent. *Id.*

Here, Plaintiffs do not seek to enforce the provisions of the FDCA, instead they allege that Defendants fraudulently and misleadingly promoted their opioids. These allegations are of the type that would traditionally be brought as state law claims and, therefore, are not preempted.

3. Obstacle Preemption

The Manufacturers next argue that Plaintiffs' diversion monitoring theory "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" under the FDCA. (R. 499-1, PageID# 7691, *citing Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372-73 (2000)). They frame the allegations as an assertion that the Manufacturers "had a duty not to sell their prescription opioids due to concerns with opioid diversion," and a prayer for damages and an injunction against any further violations. *Id.* at PageID# 7693. Defendants contend that "allowing these claims to proceed would undermine the FDA's decision to make (and keep) [the Manufacturers'] prescription opioids available to the public" and are thus preempted. *Id.* (internal quotation marks omitted).

The complaint cannot be reasonably construed as alleging that Defendants should have stopped selling opioids altogether, but rather alleges that they failed in their duty to prevent or actively concealed opioid diversion and misuse. Plaintiffs contend that their allegations focus on Defendants' "duty to use due care in selling their dangerous products and that they are liable for failing to use such care." (R. 654, PageID# 15832). Plaintiffs further argue that their diversion and monitoring claims are consistent with federal standards of care applicable to the sale of

opioids, and thus create no obstacle to the implementation of the FDCA. *Id.*, PageID# 15830-15832.

Federal law preempts state law under the doctrine of obstacle preemption when state law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.” *Crosby*, 530 U.S. at 372-373. State tort actions related to the sale and marketing of pharmaceuticals raise the specter of obstacle preemption. In *Wyeth v. Levine*, the Supreme Court considered obstacle preemption in the context of a state tort claim alleging that the manufacturer of Phenergan had failed to provide adequate warnings about the risks of injecting the drug. 555 U.S. 555 (2009). The Supreme Court rejected Wyeth’s obstacle preemption argument, noting that with limited resources to monitor the 11,000 drugs on the market, the FDA appears to view state tort law as a “complementary” form of drug regulation indicating:

If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's 70-year history. But despite its 1976 enactment of an express pre-emption provision for medical devices ... Congress has not enacted such a provision for prescription drugs. See *Riegel v. Medtronic, Inc.*, 552 U.S., at 327 (2008) (“Congress could have applied the pre-emption clause to the entire FDCA. It did not do so, but instead wrote a pre-emption clause that applies only to medical devices.”) Its silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness. As Justice O'Connor explained in her opinion for a unanimous Court: “The case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to stand by both concepts and to tolerate whatever tension there [is] between them.” *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 166–167, 109 S.Ct. 971, 103 L.Ed.2d 118 (1989) (internal quotation marks omitted).

Wyeth, 555 U.S. at 574-575 (internal footnotes omitted).

The Manufacturers assert that one of Congress’ core objectives in enacting the FDCA was to “ensure that any product regulated by the FDA is safe and effective for its intended use.”

FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 133 (2000). They state that courts have consistently “held that this regulatory scheme preempts any state law claim seeking to prohibit drug manufacturers from selling their FDA-approved products as permitted by FDA.” See, e.g. *Zogenix, Inc. v. Patrick*, 2014 WL 1454696, at *1-2 (D. Mass. Apr. 15, 2014); *Gross v. Pfizer, Inc.*, 825 F. Supp. 2d 654, 659 (D. Md. 2011) (requiring a drug manufacturer “to stop production of a drug” “would directly conflict with” FDA’s “sole authority ... to determine whether a drug may be marketed.”), *aff’d sub nom. Drager v. PLIVA USA, Inc.*, 741 F.3d 470 (4th Cir. 2014). Both *Zogenix* and *Gross* are distinguishable because they, respectively, involved an attempt to enforce a state regulatory ban on the sale of certain drugs and a challenge to the adequacy of label warnings approved by the FDA. By contrast, Plaintiffs here seek to enforce an alleged state law duty to, for example, monitor the sale of drugs with due care—a claim that is not inconsistent with the purposes of the FDCA, and thus not preempted.

C. Statute of Limitations

Noting that the complaint is based on facts dating back to the 1990s, the Manufacturers assert that applying the most generous of the applicable statute of limitations—the 5-year period for an OCPA claim—would bar claims relying on conduct predating early 2013. (R. 499-1, PageID# 7708-7709). Plaintiffs counter that dismissal based on affirmative defenses at the pleading stage is inappropriate where issues of fact concerning tolling exceptions exist.

Resolving a motion to dismiss based on statute-of-limitations grounds is appropriate when the undisputed facts “conclusively establish” the defense as a matter of law. *Estate of Barney v. PNC Bank*, 714 F.3d 920, 926 (6th Cir. 2013); *Cataldo v. U.S. Steel Corp.*, 676 F.3d 542, 547 (6th Cir. 2012), *cert. denied*, 568 U.S. 1157 (2013). But where there are disputed factual questions, for example “relating to the accrual date, ... claims that the defendant fraudulently

concealed facts thereby preventing the plaintiff from learning of its injury, ... and complex issues about whether information in the plaintiff's possession sufficed to alert it of the claim[.]" then a statute of limitations defense is more appropriately addressed in the context of a summary judgment motion or at trial. *Am. Premier Underwriters, Inc. v. Nat'l R.R. Passenger Corp.*, 839 F.3d 458, 464 (6th Cir. 2016); *Lutz v. Chesapeake Appalachia, LLC*, 717 F.3d 459, 473-476 (6th Cir. 2013) (reversing and remanding to the district court to resolve issue of fraudulent concealment). Moreover, parties "are entitled to have their cause tried on the merits if they can prove that the doctrine of fraudulent concealment should be applied to their case." *Jones v. TransOhio Sav. Ass'n*, 747 F.2d 1037, 1043 (6th Cir. 1984) ("We are unprepared to hold, prior to any discovery on the issue, that Appellants can prove no set of facts consistent with these allegations sufficient to toll the statute of limitations.").

The complaint alleges that the fraudulent concealment and continuing violation doctrines extend the applicable limitations periods, because "Defendants were deliberate in taking steps to conceal their conspiratorial behavior and active role in the deceptive marketing and the oversupply of opioids through overprescribing and suspicious sales, all of which fueled the opioid epidemic." (R. 514 at ¶¶770, 767-777). The complaint also alleges that Defendants, including the Manufacturers, purposefully concealed their unlawful conduct while assuring the government and the public that they were complying with applicable laws and cooperating with law enforcement to curb the opioid crisis, thereby, it is alleged, depriving Plaintiffs of any actual or implied notice of potential claims. (R. 514, ¶¶768-777). It further contends that Defendants' wrongful conduct has not ceased, continues to cause Plaintiffs' injuries, that the opioid epidemic continues to spread, and that the resulting claimed injuries are ongoing. *Id.* at ¶¶715, 718, 724, 727, 729, 744, 767-768, 780, 818, 827. These allegations are sufficient to raise a plausible

inference that the applicable limitation periods are subject to tolling.

D. Counts Three and Four: Ohio RICO Statute Claims

In Counts Three and Four, Plaintiffs allege a violation of Ohio’s Corrupt Practices Act (OCPA), O.R.C. § 2923.31 *et seq.* against the Marketing Defendants and Supply-Chain Defendants respectively. (R. 514, ¶¶939- 973). OCPA, sometimes referred to as the “Ohio RICO” statute, is “patterned after” the federal RICO statute.³⁵ Consequently, Ohio courts look to federal case law applying RICO to determine how to apply OCPA. *O’Rourke*, 640 N.E.2d at 240; *Durrani*, 2014 WL 996471, at *8.

Defendants assert that Plaintiffs’ OCPA claims must be dismissed for the same reasons as the federal RICO claims. (R. 491-1, PageID# 7489-7490; R. 499-1, PageID# 7693-7694). Because the court finds Plaintiffs have sufficiently pleaded the former, the court rejects Defendants’ argument. Defendants, however, raise an additional argument: to establish a “pattern” of racketeering activity under the OCPA, a plaintiff must allege “at least one incident other than a violation of” federal mail, wire, or security fraud statutes. O.R.C. § 2923.34(A). Plaintiffs do not challenge the existence of such a requirement, but assert they also pleaded “telecommunications fraud,” and “felony dealing in controlled substances pursuant to RICO section 1961(1)(D).” (R. 654, PageID# 15778). Plaintiffs have alleged a felony violation of the CSA, specifically § 843(a)(4)(A) (“to furnish false or fraudulent material information in, or omit any material information from, any application, report, record, or other document required to be made, kept, or filed under this subchapter or subchapter II...”). *Id.* Defendants contention—that a violation of § 843 does not constitute a predicate act—was addressed and rejected above. Thus,

³⁵ See, e.g., *Aaron v. Durrani*, 2014 WL 996471, at *8 (S.D. Ohio Mar. 13, 2014) (citing *U.S. Demolition & Contracting v. O’Rourke*, 640 N.E.2d 235, 240 (Ohio Ct. App. 1994)).

Defendants' motion to dismiss the OCPA claims should be denied.

E. Ohio Product Liability Act and Abrogation

The Distributors, joined by the Pharmacies and Manufacturers, argue that Plaintiffs' common law negligence and public nuisance claims, as well as Plaintiffs' statutory public nuisance claim, should be dismissed because they are abrogated by the Ohio Product Liability Act (OPLA), O.R.C. §§ 2307.71 through 2307.80. (R. 491-1, PageID# 7492-7496, 7502-7505; R. 497-1, PageID# 7599; R. 499-1, PageID# 7695). OPLA, by its terms, abrogates a significant swath of common law tort litigation. O.R.C. § 2307.71(B) expressly states that "Sections 2307.71 to 2307.80 of the Revised Code are intended to abrogate all common law product liability claims or causes of action." Pursuant to the statute, a product liability claim is defined as follows:

"Product liability claim" means a claim or cause of action that is asserted in a civil action pursuant to sections 2307.71 to 2307.80 of the Revised Code and that seeks to recover compensatory damages from a manufacturer or supplier for death, physical injury to person, emotional distress, or physical damage to property other than the product in question, that allegedly arose from any of the following:

- (a) The design, formulation, production, construction, creation, assembly, rebuilding, testing, or marketing of that product;
- (b) Any warning or instruction, or lack of warning or instruction, associated with that product;
- (c) Any failure of that product to conform to any relevant representation or warranty.

"Product liability claim" also includes any public nuisance claim or cause of action at common law in which it is alleged that the design, manufacture, supply, marketing, distribution, promotion, advertising, labeling, or sale of a product unreasonably interferes with a right common to the general public.

O.R.C. § 2307.71(A)(13).³⁶ Thus, there are essentially two types of product liability claims that fall under OPLA’s abrogation provisions: (1) product-related causes of action seeking compensatory damages for physical injury or for physical property damage (other than the product in question); and (2) public nuisance-type actions alleging unreasonable interference with a right common to the general public.³⁷

1. Abrogation of Negligence Claim

The Distributors argue that Plaintiffs’ common law negligence claim is, “at its core, a product liability claim—precisely the kind of claim abrogated by the OPLA.” (R. 491-1, PageID# 7504, *citing Volovetz v. Tremco Barrier Sols., Inc.*, 74 N.E.3d 743, 753 (Ohio. Ct. App. 2016) (stating courts look to “[t]he essential nature of the substantive allegations of the plaintiff’s claim, not the artificial label attached to the claim”)). Plaintiffs argue that their negligence claim is not abrogated because they do not seek compensation for physical injuries caused by Defendants’ products, but rather “to recover for economic harms inflicted on their communities by Defendants’ conduct in marketing and distributing their products.” (R. 654, PageID# 15799). Plaintiffs’ negligence action does not implicate a Type 2 product liability claims, as it does not allege an unreasonable interference with a right common to the general public. It does, however, potentially implicate a Type 1 product liability claim, as Plaintiffs do not challenge that their action involves the “design, formulation, production, construction, creation, assembly, rebuilding, testing, or marketing of that product.” O.R.C. § 2307.71(A)(13)(a). Nevertheless,

³⁶ The last paragraph emphasizing the inclusion of public nuisance claims was added by amendment and went into effect on August 1, 2007. *State ex rel. Ohio Gen. Assembly v. Brunner*, 873 N.E.2d 1232, 1235 (Ohio, 2007).

³⁷ For the sake of brevity, these will be referred to as “Type 1” and “Type 2” product liability claims respectively.

Plaintiffs assert that OPLA divides compensatory damages into two distinct categories: “harm” and “economic loss.” (R. 654, PageID# 15798). They maintain that only claims for “harm” constitute “product liability claims” under OPLA, whereas, “claims solely for ‘economic loss’ are expressly exempted from the statute and remain available at common law.” *Id.* The complaint alleges Defendants breached their duties resulting in “economic damages including, but not limited to, significant expenses for police, emergency, health, prosecution, corrections, rehabilitation, and other services,” as well as “non-physical property damage, and damage to its proprietary interests.”³⁸ (R. 514 at ¶¶1062-1063). Thus, the dispositive issue is whether Plaintiffs’ negligence action seeks to recover damages for a loss defined as “harm” by OPLA.

The statute also clarifies that injuries defined as “harm” do not constitute “economic loss” under OPLA, O.R.C. § 2307.71(A)(2). OPLA defines “economic loss” as “direct, incidental, or consequential pecuniary loss, including, but not limited to, damage to the product in question, and nonphysical damage to property other than that product.” *Id.* Damages that fall into this category are excluded from the definition of “harm.” O.R.C. § 2307.71(A)(7). Type 1 product liability claims encompass claims for compensatory damages for death, physical injury to person, emotional distress, or physical damage to property other than the product in question—the same categories of injuries defined as “harm” by O.R.C. § 2307.71(A)(7).

These distinctions are crucial with respect to Type 1 actions, as another section of OPLA states that: “Any recovery of compensatory damages for economic loss based on a claim that is asserted in a civil action, *other than a product liability claim*, is not subject to sections 2307.71 to 2307.79 of the Revised Code, but may occur under the common law of this state or other

³⁸ Though Plaintiffs allege an unreasonable interference with a right common to the general public with their common law public nuisance claim, pleading in the alternative is permissible.

applicable sections of the Revised Code.” O.R.C. § 2307.72(C) (emphasis added). Because civil actions that implicate Type 1 product liability only fall within OPLA’s ambit if they allege harm, a claim for solely economic loss by its very definition excludes harm and is not abrogated. This natural reading of the statutory language was confirmed by an Ohio Supreme Court decision, which predated the 2007 amendment:

[O.R.C. §] 2307.72 makes it clear that although a cause of action may concern a product, it is *not a product liability claim* within the purview of Ohio’s product liability statutes *unless it alleges damages other than economic ones*, and that a failure to allege other than economic damages does not destroy the claim, but rather removes it from the purview of those statutes.

LaPuma v. Collinwood Concrete, 661 N.E.2d 714, 716 (Ohio 1996) (emphasis added); *Volovetz*, 74 N.E.3d at 752 (acknowledging *LaPuma*’s holding in a footnote, but finding that plaintiff’s negligence claim was barred because it sought recovery for compensatory damages stemming from physical damage to property).

Because Plaintiffs’ negligence claim seeks only damages for non-physical property damage and expenses related to governmental expenditures, it is not abrogated by OPLA to the extent it seeks recovery solely for economic loss and not for harm.³⁹

2. Abrogation of Public Nuisance Claims

Plaintiffs’ Fifth (“Statutory Public Nuisance”) and Sixth (“Common Law Absolute Public Nuisance”) Claims for Relief allege that Defendants created and maintained a public nuisance in the marketing and distribution of prescription opioids. (R. 514 at ¶¶974-1038). Defendants assert

³⁹ Defendants argue that framing Plaintiffs’ injury as economic loss elevates form over substance, and that the personal injury to the users of opioids is the gravamen of the claim. (R. 744, PageID# 17663-17664). The court cannot find, without the benefit of any factual discovery, that *all* of Plaintiffs’ claimed injuries stem from death, physical injuries, or physical damage to property.

that Plaintiffs’ public nuisance claims are abrogated by OPLA and can only be brought as product liability claims under OPLA, if at all.⁴⁰ (R. 491-1, PageID# 7492-7496). OPLA was amended in 2007 to expressly include in the definition of a “product liability claim” “any public nuisance claim or cause of action at common law in which it is alleged that the design, manufacture, supply, marketing, distribution, promotion, advertising, labeling, or sale of a product unreasonably interferes with a right common to the general public.” O.R.C. § 2307.71(A)(13).

a. Application to Statutory Public Nuisance Claim

Defendants contend that the reference to “*any* public nuisance claim” abrogates both common law *and* statutory public nuisance claims (R. 744, PageID# 17658-17659), while Plaintiffs contend that statutory public nuisances are not abrogated because the phrase “at common law” in the statute modifies both “public nuisance claim” and “cause of action.” (R. 654, PageID# 15729). Under Ohio law, “[t]o determine the intent of the legislature,” a court must “first look to the plain language of the statute,” and if it is “plain and unambiguous,” the statute should be applied as written. *State v. Gordon*, 2018 WL 2356650, at *2 (Ohio May 23, 2018) (citations omitted). The court finds the phrase “any public nuisance claim or cause of action at common law” to be ambiguous. Accordingly, the court looks to the legislative history, which notes:

SECTION 3. The General Assembly declares its intent that the amendments made by this act to sections 2307.71 and 2307.73 of the Revised Code are not intended to be substantive but are intended to clarify the General Assembly’s original intent in enacting the Ohio Product Liability Act, sections 2307.71 to 2307.80 of the Revised Code, as initially expressed in Section 3 of Am. Sub. S.B. 80 of the

⁴⁰ “Claims that are authorized by the Ohio Products Liability Act should be pled with reference to the applicable provision of the Act.” *Greenway v. Kimberly-Clark Corp.*, 2016 WL 3460229, at *2 (N.D. Ohio June 24, 2016) (citations omitted).

125th General Assembly, to abrogate all common law product liability causes of action *including common law public nuisance causes of action, regardless of how the claim is described, styled, captioned, characterized, or designated*, including claims against a manufacturer or supplier for a public nuisance allegedly caused by a manufacturer's or supplier's product.

2006 Ohio Laws File 198 (Am. Sub. S.B. 117) (emphasis added).

Given that the legislature explained it intended to abrogate “*common law* public nuisance causes of action,” the court agrees with Plaintiffs’ statutory construction. Therefore, Plaintiffs’ *statutory* public nuisance claim in Count Five is not abrogated by OPLA.

b. Application to Common Law Absolute Public Nuisance Claim

Despite asserting that the 2007 amendment to OPLA intended to abrogate common law public nuisance actions, Plaintiffs aver that their self-styled “common law absolute public nuisance claim” is not abrogated by OPLA because their claim is an “equitable nuisance” claim. (R. 654, PageID# 15729). Plaintiffs rely on an observation from the Ohio Supreme Court in *State ex rel. Miller v. Anthony* that an abatement action was “not a common law action, but a summary proceeding more in the nature of a suit in equity.” 647 N.E.2d 1368, 1371 (Ohio 1995) (*quoting Cameron v. United States*, 148 U.S. 301, 304 (1893)). The court does not construe the *dicta* from this decision as an affirmative finding that an absolute public nuisance claim is not a common law cause of action within the meaning of OPLA.⁴¹ Moreover, “the distinction between legal and

⁴¹ Notably, *State ex rel. Miller* did not involve an absolute public nuisance action, but instead considered whether a nuisance abatement action brought pursuant to statute—O.R.C. § 3719.10—required a jury trial under Ohio’s constitution. The court concluded that a jury trial was not required because “the nuisance abatement provisions of R.C. Chapter 3767 are equitable in nature and not created by common law.” 647 N.E.2d at 1371. Thus, it appears the court was focused on the equitable nature of the abatement remedy. Furthermore, by Plaintiffs’ logic, the statutory-based nuisance action in *State ex rel. Miller* would not be considered a statutory nuisance claim simply because the court characterized the remedy as equitable in nature. The court declines to elevate form over substance.

equitable claims [has been] abolished.” *Hodges v. Ettinger*, 189 N.E. 113, 115 (Ohio 1934).

Finally, numerous courts, including a recent decision of the Sixth Circuit Court of Appeals, have recognized that an absolute public nuisance claim in Ohio is a common law action.

Under Ohio law, *a common law public nuisance* is “an unreasonable interference with a right common to the general public.” Examples of such rights, from Ohio and elsewhere, include: a right of public passage (e.g., obstruction of highways); a right to use public space (e.g., pollution of fisheries); a right to navigable waterways (e.g., obstruction of public streams); a right to public health (e.g., exposure to diseased animals); a right to public safety (e.g., negligent marketing/sale of dangerous weapons); a right to public morality (e.g., houses of ill-repute); a right to public peace (e.g., excessive noise); and a right to public comfort (e.g., excessive odors or fumes).

Ohio law recognizes two types of public nuisances: qualified and absolute. A qualified public nuisance mirrors a negligence tort.... An absolute public nuisance, sometimes called nuisance per se, comes in two forms, one requiring more evidence of intent (akin to an intentional tort), the other requiring less (akin to a strict liability tort). The action thus requires either the “intentional” creation of a public nuisance or “an abnormally dangerous condition that cannot be maintained without injury to property, no matter what care is taken.”

City of Cincinnati v. Deutsche Bank Nat'l Trust Co., 863 F.3d 474, 477 (6th Cir. 2017) (emphasis added); *see also Cleveland v. JP Morgan Chase Bank, N.A.*, 2013 WL 1183332, at *3 (Ohio Ct. App. Mar. 21, 2013) (describing a public nuisance claim as a common law tort action used to vindicate interference with a general public right); *Brown v. Scioto Cty. Bd. of Commrs.*, 622 N.E.2d 1153, 1158 (Ohio Ct. App. 1993) (describing the common law elements of a public nuisance claim and recognizing that, in addition, there are also statutorily defined public nuisances).

Plaintiffs concede that a public nuisance claim, which they label as an “equitable” action, requires an unreasonable interference with a right common to the general public. (R. 654, PageID# 15719). The Sixth Circuit ascribed the same elements to common law public nuisance claims under Ohio law. *Deutsche Bank Nat'l Trust Co.*, 863 F.3d at 477. These are identical

causes of action that are not derived from statute. Under Plaintiffs’ reasoning, common law public nuisance claims essentially do not exist in Ohio, because public nuisance claims are properly designated as suits arising in equity. Such a conclusion is untenable, as it would render the Ohio Legislature’s 2007 amendment a nullity.⁴² Furthermore, Plaintiffs’ argument is contrary to the only Ohio decision that appears to have squarely addressed the operation of the 2007 amendment. *See City of Toledo v. Sherwin-Williams Co.*, 2007 Ohio Misc. LEXIS 5632, 2007 WL 4965044 (Ohio C.P. December 12, 2007) (finding that plaintiff’s public nuisance claim was “expressly subsumed by the OPLA”). Thus, the court finds that Plaintiffs’ absolute public nuisance claim constitutes a common law public nuisance claim and, therefore, falls within the purview of OPLA.

However, Plaintiffs raise an additional argument as to why their absolute public nuisance claim should not be construed as abrogated by OPLA—that the 2007 amendment that added the Type 2 product liability claims definition should be read as covering only those public nuisance actions that seek compensatory damages defined as harm elsewhere in the statute. (R. 654, PageID# 15730). This argument is similar to Plaintiffs’ argument above with respect to OPLA’s inapplicability to their negligence claim. Plaintiffs’ argument here is contrary to the plain language of the statute. O.R.C. § 2307.71, as amended, abrogated Type 2 claims—public nuisance claims alleging that “the design, manufacture, supply, marketing, distribution, promotion, advertising, labeling, or sale of a product *unreasonably interferes with a right*

⁴² In other words, Plaintiffs contend that non-statutory public nuisance actions in Ohio are equitable actions not common-law actions, and the 2007 amendment applies only to common law public nuisance actions. Such a result would completely frustrate the Ohio Legislature’s clear intent to abrogate common-law public nuisance actions, as the amendment would have no applicability.

common to the general public.” (emphasis added). Notably absent from the Type 2 product liability definition is the language contained in Type 1 claims that apply only to actions seeking compensatory damages for “death, physical injury to person, emotional distress, or physical damage to property other than the product in question” (*i.e.* “harm”). O.R.C. § 2703.71(A)(13). Thus, the distinction between harm and economic loss is conspicuously absent in the Type 2 definition of product liability claims.⁴³ Therefore, the issue of whether Plaintiffs’ damages under its public nuisance theory are properly categorized as economic loss is immaterial.

Consequently, O.R.C. § 2307.72(C), which states that “[a]ny recovery of compensatory damages for economic loss based on a claim that is asserted in a civil action, *other than a product liability claim*, is not subject to [OPLA]. . . .” is also inapplicable. The Ohio Supreme Court’s holding in *LaPuma* interpreted OPLA as it existed in 1996; it did not create a judicial rule exempting product liability claims if they asserted only economic loss. 661 N.E.2d at 716. Before the 2007 amendment, only the Type 1 definition of product liability claims existed, and the definition expressly excluded claims for economic loss rather than harm. This distinction was not maintained with respect to the Type 2 definition. Therefore, Plaintiffs’ argument—that its absolute public nuisance claim is not abrogated because it seeks to recover only economic loss—

⁴³ The argument that the harm requirements of Type 1 claims should be bootstrapped to Type 2 claims is not well taken. As noted above, the court should apply the plain language of the statute where it is unambiguous. Although this court above found that the statute was ambiguous with respect to the question of whether the term “common law” modified both the phrase “any public nuisance claim” and “cause of action,” the decision not to include the preexisting language from the Type 1 definition into the Type 2 definition speaks volumes. Had the legislature intended such limiting language in the application of OPLA as it relates to public nuisance claims, it could easily have repeated the language contained in the Type 1 definition. It opted not to do so. It is also telling that the Type 2 definition was not made a subsection of the Type 1 definition, revealing a clear intent to create an alternative or additional definition of a “product liability claim.”

does not exempt its common law public nuisance claim from OPLA. It is recommended that Count Six be dismissed.

F. Count Five: Statutory Public Nuisance

Count Five alleges a statutory public nuisance against all Defendants. (R. 514, PageID# 11208). It seeks “abatement, recovery of abatement costs, injunctive relief, and to prevent injury and annoyance from any nuisance,” as well as “all other legal and equitable relief as allowed by law.” *Id.* at ¶¶995-996.

The Pharmacies and Distributors assert that, among the Plaintiffs, only the Summit County Prosecutor may maintain a statutory public nuisance action brought pursuant to O.R.C. §4729.35. (R. 491-1, PageID# 7501; 497-1, PageID# 7608-7609; R. 742, PageID# 17613-17615). In addition, the Distributors and Manufacturers assert that Plaintiffs’ remedies for a statutory public nuisance are limited to an injunction. (R. 491-1, PageID# 7501-7502; R. 499-1, PageID# 7700, n. 39). This latter argument does not provide a basis for dismissal. While the category of damages recoverable may be a legal issue proper for the court’s consideration, Defendants have not identified any authority supporting their proposed statutory construction. *Id.*

1. Ohio Rules of Statutory Interpretation and Applicable Laws

First, under the express rules of Ohio statutory construction, a court should construe various statutes in harmony unless their provisions are irreconcilably in conflict:

If a general provision conflicts with a special or local provision, they shall be construed, if possible, so that effect is given to both. If the conflict between the provisions is irreconcilable, the special or local provision prevails as an exception to the general provision, unless the general provision is the later adoption and the manifest intent is that the general provision prevail.

O.R.C. §1.51; *see also United Tel. Co. v. Limbach*, 643 N.E.2d 1129, 1131 (Ohio 1994)

(“All provisions of the Revised Code bearing upon the same subject matter should be

construed harmoniously. ... [and] in the interpretation of related and co-existing statutes must harmonize and give full application to all such statutes unless they are irreconcilable and in hopeless conflict.”) (citations omitted).

The following Ohio statutes address the issue of public nuisance and are relevant to the court’s discussion. First, Chapter 3767 of the Ohio Revised Code addresses nuisances generally, and gives several definitions of a nuisance, including the following:

“That which is defined and declared by statutes to be a nuisance.” O.R.C. §

3767.01(C)(1). A separate chapter of the Ohio Revised Code, dealing with occupations and professions, identifies one such public nuisance:

The violation by a pharmacist or other person of any laws of Ohio or of the United States of America or of any rule of the board of pharmacy controlling the distribution of a drug of abuse as defined in section 3719.011⁴⁴ of the Revised Code or the commission of any act set forth in division (A) of section 4729.16 of the Revised Code, is hereby declared to be inimical, harmful, and adverse to the public welfare of the citizens of Ohio and to constitute a public nuisance. The attorney general, the prosecuting attorney of any county in which the offense was committed or in which the person committing the offense resides, or the state board of pharmacy may maintain an action in the name of the state to enjoin such person from engaging in such violation. Any action under this section shall be brought in the common pleas court of the county where the offense occurred or the county where the alleged offender resides.

O.R.C. §4729.35. Returning to the general chapter on nuisances, O.R.C. § 3767.03 states that:

“[w]henever a nuisance exists,” an authorized party⁴⁵ “may bring an action in equity in the name of the state ... to abate the nuisance and to perpetually enjoin the person maintaining the

⁴⁴ O.R.C. §§ 3719.01(R) & 3719.011 define opiate as “a drug of abuse.”

⁴⁵ O.R.C. § 3767.03 includes a significantly broader list of authorized parties who may maintain a public nuisance action than O.R.C. § 4729.35, as it includes the attorney general, the village solicitor, the city or township law director, the county prosecutor, or any person who is a citizen of the county in which the nuisance exists so long as the action is brought in the name of the state. The ramifications of this discrepancy is addressed below.

nuisance from further maintaining it.”

2. Available Remedies

Defendants assert that any violation of O.R.C. § 4729.35 limits Plaintiffs’ recovery to injunctive relief and that abatement costs are unrecoverable. (R. 491-1, PageID# 7501-7502; R. 499-1, PageID# 7700). However, Defendants’ argument—that O.R.C. § 4729.35’s provision that an authorized individual “may maintain an action in the name of the state to enjoin” a public nuisance is tantamount to a limitation on the remedies available—is an untenable interpretation of the plain text of the statute. Nothing in this statute can reasonably be construed as addressing or expressly limiting the categories of relief available for the nuisance. Rather, it identifies and defines a public nuisance, identifies who may bring the action to enjoin a nuisance, and finally where the claim should be brought. Further, Defendants’ interpretation of the remedies available for a violation of O.R.C. § 4729.35 is not supported by any authority cited in their briefs.

Finally, Defendants’ interpretation of O.R.C. § 4729.35 contravenes Ohio’s laws on statutory construction, as stated above, that require a court to construe statutes so as to give effect to both the special and general provisions, and to construe all provisions of the Revised Code bearing upon the same subject as being in harmony. Defendants’ construction does the opposite—it manufactures a conflict where none exists on the face of the statute. Because O.R.C. § 4729.35 is silent as to what remedies are available and the more general statute explains that an action seeking to abate a nuisance is equitable in nature, the court declines to recommend limiting the recovery or remedies available for a violation of O.R.C. § 4729.35 from what is typically recoverable in public nuisance actions.

3. City of Akron's Authority to Bring Public Nuisance Suit

Turning to the argument that the City of Akron is barred from bringing a nuisance claim, Defendants assert that O.R.C. § 4729.35 limits the authority for bringing an action to enjoin a violation of Ohio or federal drug laws to the state attorney general, the county prosecutor of the county in which the offense occurred, and the state board of pharmacy. Plaintiffs' contention that the City of Akron may, nevertheless, maintain a nuisance action for an ostensible violation of federal or Ohio drug laws based on other more generalized nuisance statutes flies in the face of the another portion of the Revised Code that they specifically rely upon—O.R.C. § 1.47 ("In enacting a statute, it is presumed that: (B) The entire statute is intended to be effective").⁴⁶ Plaintiffs' position—that municipalities could maintain a statutory public nuisance action for violation of a state or federal drug law—would eviscerate the express statutory provision limiting who can bring suit. Plaintiffs' reliance on *State ex rel. DeWine v. Fred's Party Center, Inc.*, 13 N.E.3d 699 (Ohio Ct. App. 2014) is misplaced. (R. 654, PageID# 15726). Therein, not only was the suit brought by the Ohio Attorney General, but the court's passing reference to O.R.C. § 4729.35 in a footnote neither states nor implies that any party, other than the attorney general,

⁴⁶ Plaintiffs also rely on O.R.C. § 715.44, which states as follows:

A municipal corporation may:

(A) Abate any nuisance and prosecute in any court of competent jurisdiction, any person who creates, continues, contributes to, or suffers such nuisance to exist;

(C) Prevent injury and annoyance from any nuisance;

the county prosecutor, or the board of pharmacy is vested with authority to bring an action under that statute. *Id.* at n. 1. Although O.R.C. § 4729.35 is not the exclusive avenue for a municipal plaintiff to bring a public nuisance claim, the City of Akron cannot claim that the very nuisance it seeks to abate is the one caused by a violation of Ohio or federal drug laws, as set forth in O.R.C. § 4729.35, but then attempt to circumvent the limitations on who may bring such a suit as set forth in the same statute simply by claiming to rely on a different portion of the Revised Code. In the complaint, Plaintiffs, including the City of Akron, clearly identify the public nuisance they seek to enjoin as violations of Ohio or federal drug laws (or the rules of the board of pharmacy). (R. 514, PageID# 7068, ¶¶979, 983-984, 986, 988). As such, the City of Akron lacks standing to pursue a statutory public nuisance claim based on violations of Ohio or federal drug laws, or the rules of the board of pharmacy.

4. Sufficiency of the Factual Allegations

The Manufacturers argue that Plaintiffs' statutory nuisance claim should be dismissed for failure to allege facts demonstrating a statutory violation. *See Brown*, 622 N.E.2d at 1158 (explaining that Ohio statutes and regulations that define certain conduct as being a public nuisance "amount to a legislative declaration that the proscribed conduct is an unreasonable interference with a public right"); O.R.C. § 3767.01(C)(1) (defining "nuisance" as "that which is defined and declared by statutes to be a nuisance"). The Manufacturers' statement that they "have complied with all relevant federal and state controlled substances requirements" (R. 499-1, PageID# 7702) is merely an assertion of fact that is disputed by Plaintiffs and does not support dismissal at this stage. They also contend that the alleged violations of Ohio law apply only to distributors and not to pharmaceutical manufacturers. (R. 499-1, PageID# 7700-7701; R. 746, PageID# 17724-17725). Plaintiffs state that certain other laws and rules governing the

distribution of controlled substances do apply to the Manufacturers' alleged conduct, including those requiring them to maintain diversion controls and to create a system to disclose suspicious orders, report such orders, and adhere to sales quotas set by the DEA. (R. 654, PageID# 15726-15728, *citing* R. 514 at ¶¶504, 507, 510, 863, 915, 961). The complaint alleges that all Defendants have aided and abetted the violation of federal and state laws controlling the distribution of a drug of abuse as defined in O.R.C. § 3719.011.⁴⁷ (R. 514 at ¶¶981-986).

The complaint also alleges violations of O.R.C. § 2925.02(A)(1) and (3), which prohibit the administering, inducing, or causing another to use a controlled substance “[b]y force, threat, or deception” (§ 2925.02(A)(1)), as well as the administering, inducing, or causing another to use such a substance “by any means,” with the additional requirement that the actions “cause serious harm” or “cause the other person to become drug dependent” (§ 2925.02(A)(3)). (R. 514 at ¶¶986-987). The Manufacturers argue that to the extent these violations are asserted in an attempt by Plaintiffs to hold them liable for failing to stop the sale of prescription opioids that have been approved by the FDA and are regulated by the DEA, any such claim is preempted. (R. 499-1, PageID# 7701-7702). But nowhere in the complaint is it alleged that the Manufacturers should be prevented from operating their business in a lawful manner; rather, Plaintiffs seek to abate the alleged public nuisance.

Like the Manufacturers, the Pharmacies assert that the complaint fails to allege specific details of nuisance-creating conduct on their part affecting Summit County or even the State of Ohio and that the complaint contains “no more than conclusory factual allegations ...” (R. 497-1,

⁴⁷ The Manufacturers also assert that Plaintiffs' Opposition cites to statutory violations not specifically pled, but the complaint identifies specific statutes as bases for alleged liability and also states that the claimed violations include, but are not limited to, conduct proscribed by Ohio and federal law. (R. 514 at ¶984).

PageID# 7609-7610). They concede, however, that Plaintiffs have alleged several violations of Ohio and federal law, but protest that the allegations are not sufficiently specific with respect to recordkeeping defaults and contend the allegations that they failed to maintain effective controls against diversion or failed to disclose suspicious orders are implausible. *Id.* Indeed, the complaint contains allegations that the Pharmacies engaged in misconduct and violated federal and state laws, and references numerous fines and settlements involving the Pharmacies. (R. 514, ¶¶ 504, 612-659, 684-686). Furthermore, where the facts at issue may be in the control of others, dismissal prior to discovery is not appropriate. *Ohio Pub. Emps. Ret. Sys. v. Fed. Home Loan Mortg. Corp.*, 830 F.3d 376, 383 (6th Cir. 2016) (explaining that the pleading standards only require enough facts to demonstrate a reasonable expectation that discovery will reveal evidence to support the allegations).

5. Safe Harbor

“Ohio courts have long imposed the following concrete limitation on public nuisance claims: What the law sanctions cannot be held to be a public nuisance.” *City of Cleveland v. Ameriquest*, 621 F. Supp.2d 513, 526 (N.D. Ohio 2009), *aff’d*, 615 F.3d 496 (6th Cir. 2010) (citations omitted). The Manufacturers claim that they are shielded from nuisance liability by virtue O.R.C. § 2925.02(B), which provides a “safe harbor” for persons whose conduct is in accordance with Ohio controlled substance regulations. (R. 499-1, PageID# 7001-7002). They assert that they “have complied with all relevant federal and state controlled substances requirements.” *Id.*

But as *Ameriquest* makes clear, safe harbor immunity from nuisance liability is available only to those who perform in accordance with their applicable regulatory obligations. 621 F. Supp. 2d at 528 (“Under a long line of decisions, a showing that the challenged conduct is

subject to regulation and was performed in conformance therewith insulates such conduct from suit as a public nuisance”). The complaint alleges that all Defendants failed to do so. (R. 514 at ¶¶981-988). It also alleges misconduct unrelated to Defendants’ respective regulated activities, for example, as to the Manufacturers, an extensive deceptive marketing scheme that intended to change the perception of opioids and boost sales by misleading doctors and the public about the risks of long-term opioid use. (R. 514 at ¶¶174-179, 989).

While regulatory oversight is a factor to be considered when determining the sufficiency of a public nuisance claim, “extensive regulation does not automatically bar a public nuisance claim.” *City of Cleveland v. JP Morgan Chase Bank, N.A.*, 2013 WL 1183332, *6 (Ohio Ct. App. March 21, 2013); *Cincinnati v. Beretta*, 768 N.E.2d at 1143. The *Beretta* court rejected defendants’ assertion that they were engaged in “legislatively authorized conduct,” and were not subject to liability. 768 N.E.2d at 1143. The court concluded that “even though there exists a comprehensive regulatory scheme involving the manufacturing, sales, and distribution of firearms, ... the law does not regulate the distribution practices alleged in the complaint,” *i.e.*, practices that “fostered the criminal misuse of firearms [and] helped sustain the illegal firearms market in Cincinnati” *Id.* at 1140. Contrary to Manufacturers’ contention that the complaint is defective because it fails to plead “any facts to show that any Manufacturer Defendant somehow deceived a particular resident in Summit County into using opioids, much less into becoming opioid dependent,” that level of specificity is not required prior to discovery. (R. 499-1, PageID# 7702).

Accordingly, it is recommended that Defendants’ motions to dismiss be partially granted to the extent they seek to bar the City of Akron from maintaining a statutory public nuisance action based on either: (1) a violation of an Ohio or federal drug law; or (2) any rule of the board

of pharmacy controlling the distribution of a drug of abuse. It is otherwise recommended that Defendants' motions to dismiss count five, or to limit Plaintiffs' statutory remedies, be denied.⁴⁸

G. Count Seven: Negligence

The complaint alleges a negligence claim against all Defendants. (R. 514, PageID# 11220). A negligence claim must allege (1) a duty owed by the defendant to the plaintiff to conform to a certain standard of conduct, (2) that the defendant breached that duty, and (3) that the breach of the duty proximately caused the plaintiff's injury. *Cromer v. Children's Hosp. Med. Ctr. of Akron*, 29 N.E.3d 921, 928-929 (Ohio 2015). Defendants challenge the sufficiency of the complaint with respect to the first and third elements. (R. 491-1, PageID# 7505-7513, 7515-7519; R. 497-1, PageID# 7599-7608; R. 499-1, PageID# 7702-7703).

1. Duty of Care

"The existence of a duty is a question of law for a court to determine." *Mussivand v. David*, 544 N.E.2d 265, 270 (Ohio 1989) ("There is no formula for ascertaining whether a duty exists. Duty...is the court's expression of the sum total of those considerations of policy which lead the law to say that the particular plaintiff is entitled to protection.") (citations and quotations omitted). "The Ohio Supreme Court has explained that '[t]he existence of a duty depends on the foreseeability of the injury.'" *Jaycox v. Setty Family Veterans Residential Care Home*, 2004 WL

⁴⁸ Although the Distributors broadly argued that both Plaintiffs' negligence and nuisance claims should be dismissed based on the economic loss doctrine, they made no attempt to distinguish between common law public nuisance claims and statutory public nuisance claims. (R. 491-1, PageID# 7513-7514; R. 744, PageID# 17672-17673). "The doctrine bars tort plaintiffs from recovering purely economic loss that 'do not arise from tangible physical injury' to persons or property.'" *Deutsche Bank*, 863 F.3d at 477 (quoting *Queen City Terminals v. Gen. Am. Trans.*, 653 N.E.2d 661, 667 (Ohio 1995)). The movant has presented the court with no compelling reason to apply such a tort doctrine to a statutory claim, especially where it does not appear that Plaintiffs seeks any relief beyond that which is permitted by statute.

1171348, *3 (6th Cir. May 24, 2004) (quoting *Meniffee v. Ohio Welding Products, Inc.*, 472 N.E.2d 707, 710 (Ohio 1984)). Moreover,

The concept of foreseeability is an important part of all negligence claims, because “[t]he existence of a duty depends on the foreseeability of the injury.” *Meniffee* at 77, 472 N.E.2d 707. As a society, we expect people to exercise reasonable precautions against the risks that a reasonably prudent person would anticipate. *Commerce & Industry Ins. Co. v. Toledo*, 45 Ohio St.3d 96, 98, 543 N.E.2d 1188 (1989). Conversely, we do not expect people to guard against risks that the reasonable person would not foresee. *Meniffee* at 77, 472 N.E.2d 707; Keeton, Dobbs, Keeton & Owen, Prosser and Keeton on the Law of Torts, Section 43, 280 (5th Ed.1984). The foreseeability of the risk of harm is not affected by the magnitude, severity, or exact probability of a particular harm, but instead by the question of whether some risk of harm would be foreseeable to the reasonably prudent person. See *Gedeon v. E. Ohio Gas Co.*, 128 Ohio St. 335, 339, 190 N.E. 924 (1934). Accordingly, the existence and scope of a person's legal duty is determined by the reasonably foreseeable, general risk of harm that is involved.

Cromer, 29 N.E.3d at 928-29 (“The existence of an actor’s duty to another person usually arises from the foreseeability of injury to someone in that other person’s ‘general situation.’”) (quoting *Gedeon*, 190 N.E. at 926). The “foreseeability of harm usually depends on the defendant’s knowledge.” *Meniffee*, 472 N.E.2d at 710. But in order to owe a duty of care, it is not necessary that the defendant foresee the injury in the precise form in which it occurred. *Bohme, Inc. v. Sprint Int’l Comm. Corp.*, 686 N.E.2d 300, 303 (Ohio Ct. App. 1996); *Pavlidis v. Niles Gun Show, Inc.*, 637 N.E.2d 404 (Ohio Ct. App. 1994) (holding that an actor cannot necessarily avoid the imposition of a legal duty merely because he did not foresee the exact consequences of his actions).

In *Cincinnati v. Beretta*, the Ohio Supreme Court addressed the question of whether gun manufacturers owed a duty of care to a local government concerning harms caused by negligent manufacturing, marketing and distributing of firearms. *Beretta* involved allegations that the defendants failed to exercise sufficient control over the distribution of their guns, thereby

creating an illegal secondary market in the weapons. The *Beretta* court concluded that the harms that resulted from selling these weapons were foreseeable—that Cincinnati was a foreseeable plaintiff. 768 N.E.2d at 1144. Plaintiffs argue that the harm caused by the marketing and distribution of opioids are similarly foreseeable.

Plaintiffs assert that Defendants have a common law duty “to not expose Plaintiffs to an unreasonable risk of harm[;] ... a legal duty to exercise reasonable and ordinary care and skill in accordance with applicable standards of conduct in manufacturing, advertising, marketing, selling and/or distributing opioids.” (R. 514 at ¶¶1040-1041). Defendants deny that they owed any common law duty to Plaintiffs. (R. 499-1, PageID# 7702-7703; R. 491-1, PageID# 7511-7512; R. 497-1, PageID# 7599-7601; R. 744, PageID# 17666-17667). Defendants claim that the common law does not recognize the duty of care that Plaintiffs assert; that Plaintiffs are actually alleging a statutory duty of care under the CSA which creates duties owed only to the DEA and the Ohio Board of Pharmacy, and which provides for no private right of action; that Plaintiffs are attempting to use negligence *per se* to plead around the absence of a private right of action; that there is no duty to prevent a third person from causing harm; and that the learned intermediary doctrine forecloses any duty running from Defendants to Plaintiffs. Moreover, Distributors deny any foreseeable harm caused by their actions and characterize themselves as mere “middlemen” who “do not write prescriptions or determine whether opioid medications are appropriate for patients” or “meet directly with patients and furnish them with opioids” as pharmacists do. (R. 491-1, PageID# 7511). The Pharmacies assert that Ohio imposes no common law duty “to exercise due care in the distribution of opioids, and specifically to detect, identify, or report suspicious orders.” (R. 497-1, PageID# 7599).

Plaintiffs, for their part, do not argue that there is a private right of action under these

statutes, but rather argue that the complaint’s references to statutes merely identified a statutory standard of care that they contend could serve as a basis to support their theories of a common law duty and breach. (R. 654, PageID# 15787). Here, Plaintiffs base their duty and breach arguments on Defendants’ own conduct—failing to report suspicious orders or otherwise act to prevent diversion—which caused their harm. (R. 514 at ¶¶546, 568-569, 607-659, 989, 1046-1071). Plaintiffs’ Opposition references allegations in their complaint to argue that Defendants sold opioids “without regard to the likelihood that the opioids would be placed in the hands of criminals, addicts, juveniles, and others not permitted to use or possess prescription opioids” (*id.* at ¶1050); that the Marketing Defendants disseminated deceptive marketing about the safety and addictiveness of opioids through front groups and KOLs (*id.* at ¶¶350-428); that Marketing Defendants funded CMEs to encourage doctors to increase their prescriptions of opioids (*id.* at ¶¶429-442); that Defendants marketed, distributed and sold opioids “in a way that created and fostered an illegal, secondary prescription opioids market that resulted in a foreseeable and unreasonable risk of harm to Plaintiffs” (*id.* at ¶1049); that Manufacturers knew of doctors who were writing large quantities of opioids “[b]ut ... were singularly focused on maintaining, capturing, or increasing their sales” (*id.* at ¶574); that the Pharmacies knew of oversupply of prescription opioids (*id.* at ¶607); that Marketing and Supply Chain Defendants were aware of suspicious orders from their facilities (*id.* at ¶¶763, 589); that Marketing Defendants provided incentives to sales representatives and ignored red flags of diversion during regular visits to pharmacies and doctors (*id.* at ¶¶516, 568-569); and their sales representatives frequently promoted opioids in Summit County (*id.* at ¶673).

Plaintiffs argue that these allegations are sufficient to establish that their resulting harm (*i.e.* dramatically increased expenditures on public health and safety) was the foreseeable and

likely result of Defendants' actions. (R. 654, PageID# 15783-15784). Taking Plaintiffs' allegations as true, Plaintiffs have stated a plausible claim that it was reasonably foreseeable that they would be forced to bear the public costs of increased harm from the over-prescription and oversupply of opioids in their communities if Defendants failed to implement and/or follow adequate controls in their marketing, sales, distribution, and dispensing of opioids.

Defendants argue, however, that Ohio law imposes no duty "to prevent a third person from causing harm to another absent a special relation between the parties." (R. 499-1, PageID# 7687; R. 497-1, PageID# 7600; R. 491-1, PageID# 7512). Defendants argue that Plaintiffs have not alleged any special relationship that would give rise to such a duty. *Id.* The defendants in *Cincinnati v. Beretta* raised a similar argument against municipal expenditures following the actions of firearm manufacturers. 768 N.E.2d at 1144-46. Therein, the city alleged that defendants marketed and distributed their firearms in such a way as to "ensure the widespread accessibility of the firearms to prohibited users" thereby fostering criminal misuse and an illegal aftermarket. *Id.* at 1140. The Ohio Supreme Court determined that the "special relationship rule [was] not determinative" because plaintiffs were not alleging a duty to control third persons. Instead, the court maintained that "the issue is whether appellees are themselves negligent by manufacturing, marketing, and distributing firearms in a way that creates an illegal firearms market that results in a foreseeable injury." *Id.* In this case, Plaintiffs' do not assert a duty to prevent the actions of third persons, but rather a duty owed by Defendants to Plaintiffs to use reasonable care in, for example, marketing, monitoring, reporting, and selling their opioids. The wrongful conduct alleged is that of Defendants, and not of third persons.

The Pharmacies contend that they do not owe a duty as a result of the learned intermediary doctrine. The learned intermediary doctrine is not applicable as explained *supra* in

the RICO analysis. Distributors also argue that any duty they may owe to “report suspicious order is a duty that was created by statute, and the duty runs to the DEA and the Ohio Board of Pharmacy, not the County.” This duty, they argue, is “unknown at common law.” They maintain that when Plaintiffs assert a common law duty of care, they are actually seeking to enforce the CSA and Ohio’s pharmacy regulations for controlled substances. (R. 491-1, PageID# 7505-7511; R. 497-1, PageID# 7602-05). Because the court finds that Plaintiffs have plausibly pleaded facts sufficient to establish that Defendants owed them a common law duty, the court does not reach this argument based upon the limited record before it.⁴⁹

2. Proximate Cause

Plaintiffs must allege facts that, if proven, plausibly establish a causal link between Defendants’ actions and Plaintiffs harm that is not too remote. The Ohio Supreme Court and the Sixth Circuit have employed the proximate cause test devised by the U.S. Supreme Court in *Holmes* in negligence cases like this one. 503 U.S. at 268-70; *see also Cincinnati v. Beretta*, 768 N.E.2d at 1147-49; *Ameriquest*, 615 F.3d at 504.

Plaintiffs argue that Defendants’ alleged negligent sales practices, including failing to comply with obligations to monitor and report suspicious orders, halt suspicious orders, and implement effective diversion controls have led directly to the creation of a population of addicted patients and nourished the illegal secondary market, both of which lie at the root of the opioid crisis, resulting in complex and costly consequences to Plaintiffs’ provision of public health, social, and criminal justice services. (R. 514 at ¶¶1040-1060).

⁴⁹ Nor is it necessary to address Defendants’ arguments with regard to negligence *per se*, as those arguments presuppose Plaintiffs’ failure to plead a common law duty.

Defendants insist that Plaintiffs' alleged injuries are far too remote and indirect to establish proximate cause. (R. 491-1, PageID# 7515-7518; R. 497-1, PageID# 7605-7608).⁵⁰ They argue that there are numerous intervening causes which break the causal link between their own actions and Plaintiffs' harms. These include the actions of prescribing doctors, criminals in the secondary market, and addicted users, among others. *Id.* Defendants also argue that Plaintiffs' harms were not proximately caused by Defendants actions, because those harms are derivative of harms sustained by third parties. Defendants urge the court to reach the same result on causation as the one reached by courts in the recent mortgage finance cases. *See JP Morgan Chase Bank*, 2013 WL 1183332, at *6; *Ameriquest*, 621 F. Supp. 2d at 536.

The Ohio Supreme Court has explained that in order to establish proximate causation, "there must be some direct relation between the injury asserted and the injurious conduct alleged." *Cincinnati v. Beretta*, 768 N.E.2d at 1148. The Ohio Supreme Court in *Beretta* adopted *Holmes*' analysis for remoteness and proximate cause, concluding that the complaint had set forth facts sufficient to establish proximate cause. As to the first factor, the court reasoned that concerns with the difficulty of proof were minimal, in part, because "the complaint...alleged that as a direct result of misconduct ...[the city] has suffered 'actual injury and damages including but not limited to, significant expenses for police, health, prosecution, emergency, corrections and other services.'" *Id.* at 1148. The second factor did not pose a problem because there was "little risk of double recovery, since [the city] is seeking recovery for injuries to itself only." *Id.* Finally, invoking the deterrence principle embedded in the third *Holmes* factor, the court stated

⁵⁰ While asserting that Plaintiffs' negligence claim should be dismissed, the Manufacturers do not meaningfully develop any new argument and adopt earlier arguments. (R. 499-1, PageID# 7702). For the reasons stated elsewhere in this report and recommendation, such reiterated arguments, including the assertion that proximate cause is lacking, fail.

that “[a]lthough appellant is indirectly attempting to protect its citizens from the alleged misconduct by the gun manufacturers and trade associations, appellant is seeking recovery for its own harm. Under these circumstances, the general interest will be best served by having this plaintiff bring this lawsuit.” *Id.* The court reversed the appellate court ruling that the city’s claims were “too remote for recovery.” *Id.*

Although the facts of this case differ in some respects from *Beretta*, its analysis of remoteness under *Holmes* is persuasive. Furthermore, the court has conducted a proximate cause analysis regarding the *Holmes* factors in section III-A-2-b above that need not be repeated here.⁵¹

Noting that Plaintiffs plead criminal acts, Defendants assert that their position is analogous to sellers who supply to independent retailers from whom drugs are obtained for diversion. *See, e.g., Ashley Cty. v. Pfizer, Inc.*, 552 F.3d 659, 663 and n.5 (8th Cir. 2009) (applying Arkansas law to find that intervening acts by retailers and methamphetamine cooks to whom they sold pseudoephedrine were independent causes relieving distributors of liability based on the legal sale of products later used for illicit purpose); *City of Philadelphia v. Beretta U.S.A. Corp.*, 277 F.3d 415, 424 (3d Cir. 2002) (affirming dismissal of public nuisance claim against gun distributors because of the many “links that separate a manufacturer’s sale of a gun to a licensee and the gun’s arrival in the illegal market through a distribution scheme that is not only lawful, but also is prescribed by statute with respect to the manufacturers’ conduct”). The

⁵¹ Although the Pharmacies were not subject to the RICO claims addressed above, the differences between the allegations against them and the remaining Defendants do not compel a different result when addressing the issue of proximate cause. The Pharmacies are alleged to have “failed to report suspicious orders, prevent diversion, or otherwise control the supply of opioids [flowing] into communities across America,” (R. 514 at ¶¶579, 607-626), and have been the subject of fines by the DEA for failing to do so. (*Id.* at ¶¶627-659). Moreover, the Pharmacies, the ultimate dispenser of opioids, are arguably a step closer to the injured parties than the other Defendants.

Distributors also argue that Plaintiffs plausibly allege that only Manufacturers could have foreseen that intervening criminal or intentional acts would occur and, therefore, do not establish that the alleged harm was foreseeable to Distributors. (R. 744, PageID# 17672, *citing Feichtner v. Ohio Dep't of Trans.*, 683 N.E.2d 112, 119-20 (Ohio Ct. App. 1995) (recognizing that there is no common law duty to anticipate or foresee criminal activity); *Volter v. C. Schmidt Co.*, 598 N.E.2d 35, 39 (Ohio Ct. App. 1991) (“Where the harm is intentionally caused by a third person and is not within the scope of the risk created by the actor’s conduct, the intentional act is considered a superseding cause because such acts are typically not foreseeable.”)).

Not only does the complaint allege that the opioid addiction epidemic and its attendant injury to government entities were foreseeable to all Defendants, it also alleges that even after Defendants were aware of the opiate addiction crisis they continued distributing commonly abused and diverted drugs in quantities and with frequency that they knew or should have known could not be justified by legitimate medical need and they manipulated quotas to evade reporting duties and maintain that inflated level of sale.⁵² (R. 514 at ¶¶18, 518, 550, 557, 565, 579, 496, 606-08, 763, 929, 1012, 1019-1020). The Distributors’ argument is also refuted by allegations that they conspired with the Manufacturers in a concerted scheme to expand the opioid market, to ensure that distribution quotas remained artificially high and that suspicious orders were not reported. (R. 514 at ¶¶760-766). In addition, Defendants’ arguments concerning third-party intervening acts and alleged superseding events raise significant factual issues not suitable for resolution on a motion to dismiss.

⁵² As the cited paragraphs illustrate, the Pharmacies’ argument to the contrary is misplaced. (R. 742, PageID# 17611). The complaint does claim the Distributors could have foreseen, and were aware of, unnecessary prescriptions and the operation of pill mills, but nevertheless supplied them.

3. Economic Loss Rule

The Defendants argue that the economic loss doctrine requires dismissal of Plaintiffs' negligence claim. (R. 491-1, PageID# 7513-7514; R. 497-1, PageID# 7601-7602.).⁵³ They assert that the doctrine prohibits a negligence claim unless the plaintiff incurred a physical injury to person or property. *Id.*; see *Corporex Dev. & Constr. Mgt., Inc. v. Shook, Inc.*, 835 N.E.2d 701, 704 (Ohio 2005); *Floor Craft Floor Covering, Inc. v. Parma Cmty. Gen. Hosp. Ass'n*, 560 N.E.2d 206, 208 (Ohio 1990); see also *Deutsche Bank Nat'l Tr. Co.*, 863 F.3d at 477 (noting, "The premise of the economic loss rule is that tort law does not impose an independent duty to avoid consequential economic damages."); *Pavlovich v. Nat'l City Bank*, 435 F.3d 560, 569 (6th Cir. 2006). Defendants also rely upon, *Queen City Terminals, Inc. v. Gen. Am. Transp.*, in which the Ohio Supreme Court held that "in order to recover indirect economic damages in a negligence action, the plaintiff must prove that the indirect economic damages arose from tangible physical injury to persons or from tangible property damage. Indirect economic damages that do not arise from tangible physical injury to persons or from tangible property may only be recovered in contract." 653 N.E.2d 661, 667 (Ohio 1995); see also *Ashtabula River Corp. Grp. II v. Contrail, Inc.*, 549 F.Supp.2d 981, 987 (N.D. Ohio 2008) (R. 744, PageID# 17675).

Plaintiffs argue that the doctrine primarily applies to bar recovery in cases between parties in a contractual relationship. See *Corporex*, 835 N.E.2d at 701; *Chemtrol Adhesives, Inc. v. Am. Mfrs. Mut. Ins. Co.*, 537 N.E.2d 624 (Ohio 1989); *Digiknow, Inc. v. PKXL Cards, Inc.*,

⁵³ Manufacturers make only cursory reference to the economic loss doctrine as a reason to dismiss Plaintiffs' negligence claim. (R. 499-1, PageID# 7702). They simply cite to *Corporex* in a bullet point, and then refer to a single paragraph of argument in their public nuisance section. Also, the Pharmacies adopt Distributors' arguments. (R. 742, PageID# 17613).

2011 WL 2899600, at *1 (Ohio Ct. App. July 21, 2011). Plaintiffs argue that the doctrine does not apply to their negligence claim because it is not based on the negligent performance of contractual duties. (R. 654, PageID# 15795-15797).

The Ohio Supreme Court in *Corporex* explained that the rule “stems from the recognition of a balance between tort law, designed to redress losses suffered by a breach of duty imposed by law to protect societal interests, and contract law, which holds that parties to a commercial transaction should remain free to govern their own affairs.” 835 N.E.2d at 704 (“Tort law is not designed to compensate parties for losses suffered as a result of a breach of duties assumed only by agreement.”). In other words, the economic loss rule recognizes that the risk of consequential economic loss is something that the parties can allocate by agreement when they enter into a contract. This allocation of risk is not possible where, as here, the harm alleged is caused by involuntary interactions between a tortfeasor and a plaintiff. Thus, courts have noted that in cases involving only economic loss, the rule “will bar the tort claim if the duty arose only by contract.” *Campbell v. Krupp*, 961 N.E.2d 205, 211 (Ohio Ct. App. 2011). By contrast, “the economic loss rule does not apply—and the plaintiff who suffered only economic damages can proceed in tort—if the defendant breached a duty that did not arise solely from a contract.” *Id.*; *see also Corporex*, 835 N.E.2d. at 705 (“When a duty in tort exists, a party may recover in tort. When a duty is premised entirely upon the terms of a contract, a party may recover based upon breach of contract.”); *Ineos USA LLC v. Furmanite Am., Inc.*, 2014 WL 5803042, at *6 (Ohio Ct. App. Nov. 10, 2014) (“[W]here a tort claim alleges that a duty was breached independent of the contract, the economic loss rule does not apply.”).

As discussed elsewhere in this opinion, Plaintiffs have pleaded facts which, if proven, plausibly establish the existence of a common law tort duty. Moreover, it would be premature on

this limited record to apply the economic-loss rule as Defendants have characterized Plaintiffs' economic damages as purely derivative of personal injuries, which if ultimately successful at summary judgment or before the trier-of-fact, could foreclose this argument. In addition, Plaintiffs have facially pled damages to their proprietary interests. (R. 514 at ¶1063). As such, Defendants have not shown that Plaintiffs' negligence claim runs afoul of the economic loss rule.

H. Count Eight: Fraud

In Count Eight, Plaintiffs assert a common law fraud claim against the Marketing Defendants. (R. 514, PageID# 11227). To state a cognizable cause of action for fraud under Ohio law, a complaint must plead the following elements:

(a) a representation or, where there is a duty to disclose, omission of a fact; (b) which is material to the transaction at hand; (c) made falsely, with knowledge of its falsity, or with such utter disregard and recklessness as to whether it is true or false that knowledge may be inferred; (d) with the intent of misleading another into relying upon it; (e) justifiable reliance upon the representation or concealment; and (f) a resulting injury proximately caused by the reliance.

Lucarell v. Nationwide Mutual Ins. Co., 97 N.E.3d 458, 472 (Ohio 2018) (citations omitted).

The briefs focus on the element of justifiable reliance. Generally, whether a plaintiff justifiably relied on an allegedly fraudulent misrepresentation or omission is a question of fact and not appropriate for determination on a motion to dismiss. *See, e.g., Jewell Coke Co., L.P. v. ArcelorMittal USA, Inc.*, 756 F. Supp. 2d 858, 867 (N.D. Ohio 2010). The Manufacturers assert that because the claim is based on alleged misrepresentations made to third parties, it fails to plead the essential element of justifiable reliance (R. 499-1, PageID# 7703). Specifically, they contend that the misrepresentations and omissions alleged by Plaintiffs were made to induce reliance by third-party payors (R. 514 at ¶1074), or directed at state and federal regulators (*id.* at ¶856), and with intent that others rely on their omissions. *Id.* at ¶1075. As such, they contend

first-party reliance is lacking.

Plaintiffs respond that the complaint avers justifiable reliance and alleges that “Plaintiffs ... did in fact rightfully, reasonably, and justifiably rely on Marketing Defendants’ representations and/or concealments both directly and indirectly ...” (R. 514 at ¶1081) and “proceeded under the misapprehension that the opioid crisis was simply a result of conduct by persons other than Defendants [and] [a]s a consequence, these Defendants prevented Plaintiffs from a more timely and effective response to the opioid crisis” (*id.* at ¶1082). (R. 654, PageID# 15801). In addition, they argue that Ohio recognizes a theory of recovery based on false statements made to third parties that are known or intended to deceive the pleader, *i.e.*,

that where a party makes false representations to another with the intent or knowledge that they be exhibited or repeated to a third party for the purpose of deceiving him or her, the third party can maintain an action in tort against the party making the false statements for the damages resulting from the fraud.

50 Ohio Jur. 3d, Fraud and Deceit § 79 (2018). “The maker of a fraudulent misrepresentation is subject to liability for pecuniary loss to another who acts in justifiable reliance upon it if the misrepresentation, although not made directly to the other, is made to a third person and the maker intends or has reason to expect that its terms will be repeated or its substance communicated to the other, and that it will influence his conduct in the transaction or type of transaction involved.” Restatement of the Law (Torts) § 533 (2018). Plaintiffs also cite to authority from the Sixth Circuit and this court recognizing that a *prima facie* common fraud claim is stated based on that theory. *See Nernberg v. Pearce*, 35 F.3d 247, 250–51 (6th Cir. 1994) (stating that “[i]t is generally accepted that a plaintiff is not required to prove direct reliance on a fraudulent misrepresentation to state a claim for fraud.”); *accord Lewis v. Horace Mann Ins. Co.*, 410 F. Supp. 2d 640, 664 (N.D. Ohio 2005) (denying summary judgment and

reasoning that reliance may be satisfied where a fraudulent statement or omission becomes known to a complainant who acts upon it, even if indirectly communicated by others) (also citing Oh. Jur.3d. Ed., Fraud & Deceit § 89, and *Lin v. Gatehouse Constr. Co.*, 616 N.E.2d 519, 524 (Ohio 1992)).⁵⁴

The Manufacturers are correct in stating that the complaint alleges that they intentionally made misrepresentations and omissions to the medical community, patients, and government regulators with the intent of inducing reliance. (R. 499-1, PageID# 7703-7704). Their contention that this claim fails by not alleging any first-party reliance, however, is not well-taken, as noted above. In addition, Plaintiffs also aver that the Manufacturers knowingly set out to convince physicians, patients and the public at large that false propositions regarding the safety and efficacy of opioids were true (R. 514, *e.g.*, ¶¶177-178, 1076-1078); issued press releases falsely minimizing the risks of addiction and abuse potential of the drugs (*id. e.g.*, ¶¶190, 340-341); and in public outreach and pronouncements, falsely portrayed their compliance with regulatory obligations, cooperation with law enforcement, and commitment to preventing diversion (*id. e.g.*, ¶¶595-98, 601-606). The complaint further alleges:

Defendants also concealed from Plaintiffs the existence of Plaintiffs' claims by hiding their lack of cooperation with law enforcement and affirmatively seeking to convince the public that their legal duties to report suspicious sales had been satisfied through public assurances that they were working to curb the opioid epidemic. They publicly portrayed themselves as committed to working diligently

⁵⁴ The cases that defendants cite, as plaintiffs note, are distinguishable because there was a lack of evidence supporting reliance. *See Lucarell*, 97 N.E.3d at 473-474 (finding that plaintiff "failed to prove that any fraudulent representation had been made to her" where fraud claim was based on misrepresentation made by defendant to lender to induce lender to approve plaintiff's business loan); *Mike McGarry & Sons, Inc. v. Constr. Res. One, LLC*, 2018-Ohio-528, ¶ 78-79 (Ohio Ct. App. Feb. 9, 2018) (reversing denial of summary judgment, reasoning that fraud claim could not be maintained where party presented no evidence that it took action in reliance on the allegedly false statement).

with law enforcement and others to prevent diversion of these dangerous drugs and curb the opioid epidemic, and they made broad promises to change their ways insisting they were good corporate citizens. These repeated misrepresentations misled regulators, prescribers and the public, including Plaintiffs, and deprived Plaintiffs of actual or implied knowledge of facts sufficient to put Plaintiffs on notice of potential claims.

Id. at ¶772. These allegations support a reasonable inference that these Defendants intended to induce Plaintiffs to rely on their false assurances and omissions in order to deter potential liability for injuries such as those alleged in the complaint. Based on the foregoing, a genuine dispute of fact exists as to whether Plaintiffs’ justifiably relied on alleged fraudulent statements and omissions, and it is not appropriately decided on a motion to dismiss.

I. Count Nine: Injury Through Criminal Acts

In Count Nine, Plaintiffs seek relief against all Defendants for injury through criminal acts pursuant to O.R.C. § 2307.60(A)(1), which states:

Anyone injured in person or property by a criminal act has, and may recover full damages in, a civil action unless specifically excepted by law, may recover the costs of maintaining the civil action and attorney’s fees if authorized by any provision of the Rules of Civil Procedure or another section of the Revised Code or under the common law of this state, and may recover punitive or exemplary damages if authorized by section 2315.21 or another section of the Revised Code.

O.R.C. § 2307.60(A)(1).⁵⁵ Defendants argue that the vast majority of courts have held that “a conviction for the alleged predicate criminal act” is required before a cause of action accrues. (R. 499-1, PageID# 7704; R. 497-1, PageID# 7614).⁵⁶ Defendants maintain that Plaintiffs have failed to allege the requisite criminal conviction against any of them and, therefore, their claims

⁵⁵ Defendants acknowledge the lone exception is inapplicable. (R. 499-1, PageID# 7704).

⁵⁶ *Citing Jane v. Patterson*, 2017 WL 1345242, at *4 (N.D. Ohio Apr. 12, 2017); *A.A. v. Otsego Local Sch. Bd. of Educ.*, 2016 WL 7387261, at *9 (N.D. Ohio Dec. 21, 2016); *Ortiz v. Kazimer*, 2015 WL 1400539, at *12 (N.D. Ohio Mar. 26, 2015), *aff’d*, 811 F.3d 848 (6th Cir. 2016); *Tri-State Comp. Exch., Inc. v. Burt*, 2003 WL 21414688, at *6 (Ohio Ct. App. June 20, 2003).

must be dismissed. *Id.* Conversely, Plaintiffs contend that the cases upon which Defendants rely are irreconcilable with a 2016 decision from the Supreme Court of Ohio—*Jacobson v. Kaforey*, 75 N.E.3d 203 (Ohio 2016). (R. 654, PageID# 15802-15805). Therein, the Ohio Supreme Court held that:

R.C. 2307.60(A)(1), by its plain and unambiguous terms, creates a statutory cause of action for damages resulting from any criminal act. The wording chosen by the Ohio General Assembly is explicit: any person “injured * * * by a criminal act has * * * a civil action” unless a civil action “is specifically excepted by law.” (Emphasis added.) R.C. 2307.60(A)(1).

Jacobson, 75 N.E.3d at 206 (emphasis in original). A few weeks before *Jacobson*, a decision from this district found that “Ohio Rev. Code § 2307.60(A)(1) clearly authorizes a civil action for damages for anyone injured by a criminal act, regardless of whether any person has pleaded guilty to or been convicted of a criminal offense.” *Chem. Bank v. Kausmeyer*, 2016 WL 7178662, at *7 (N.D. Ohio Dec. 9, 2016) (Pearson, J.) (citing *Cuyahoga Hts. Local School Dist. v. Palazzo*, 2016 WL 4037309 (Ohio Ct. App. July 28, 2016)). In addition, a recent decision from this district observed that O.R.C. § 2307.60 authorizes a civil action for damages caused by criminal acts, noting:

Interestingly, in 2007, the Ohio General Assembly amended ORC § 2307.60 to create a *presumption of civil liability* when the defendant had been convicted of a criminal violation. Am. Sub. S.B. 117. Had the General Assembly wanted to make a criminal conviction a condition precedent to establishing an ORC § 2307.60 claim, they presumably could have done so. However, the creation of this presumption does not conclusively establish that a conviction is not required for civil liability.

Accordingly, the Court will deny the motion to dismiss at this time. Defendants may renew their challenge in the form of a motion for summary judgment after discovery and further research.

Buddenberg v. Weisdack, 2018 WL 3159052, at *5-6 (N.D. Ohio June 28, 2018) (Polster, J.) (emphasis in original).

Given that Defendants, as the moving party, bear the burden of demonstrating that Plaintiffs fail to state a claim, dismissal cannot be recommended at this time, especially given the not unreasonable inference from the Ohio Supreme Court's *Jacobson* decision that a conviction may not be a necessary prerequisite.

The Pharmacies also assert that Plaintiffs have not alleged any "injur[y]" to their "person or property" pursuant to O.R.C. § 2307.60(A)(1). (R. 497-1, PageID# 7615). They allege O.R.C. § 2307.60(A)(1) does not provide for recovery for purely economic loss, but cite no authority in support of this proposition, and the statute itself does not contain such an express limitation. *Id.* The only case cited by the Pharmacies is inapposite. *See Pavlovich*, 435 F.3d at 569 ("Under Ohio law, "[t]he economic-loss rule generally prevents recovery *in tort* of damages for purely economic loss.") (emphasis added). The *Pavlovich* decision contains no discussion concerning a statutory action brought under O.R.C. § 2307.60(A)(1), and Defendants cite no other authority suggesting claims arising under that section should be construed identically to tort claims.

Finally, the Pharmacies argue that they are "specifically excepted by law" from liability under § 2307.60, by virtue of O.R.C. §§ 2925.02(B), 2925.03(B). (R. 497-1, PageID# 7615). Defendants fail to meaningfully develop this argument. The complaint alleges that Defendants are not in compliance with multiple provisions of the Revised Code rendering any exceptions unavailable. (R. 514 at ¶¶1095-1097). The Pharmacies protest that "such unsupported and generic legal conclusions should be disregarded." (R. 497-1, PageID# 7615). This statement cannot be credited, as Plaintiffs' assertions or conclusions, as Defendants phrase it, cannot be construed in a vacuum ignoring the other voluminous allegations in the complaint that support the conclusion. To the extent Defendants merely reiterate the safe harbor argument addressed above, it fails for the same reasons.

J. Count Ten: Unjust Enrichment

In Count Ten, Plaintiffs assert an unjust enrichment claim against all Defendants. (R. 514, PageID# 11235). The following elements comprise a valid unjust enrichment cause of action: “(1) a benefit conferred by a plaintiff upon a defendant; (2) knowledge by the defendant of the benefit; and (3) retention of the benefit by the defendant under circumstances where it would be unjust to do so without payment.” *Hambleton v. R.G. Barry Corp.*, 465 N.E.2d 1298 (Ohio 1984) (internal quotations omitted). Plaintiffs allege that they conferred a benefit upon Defendants “by paying for Defendants’ externalities: the cost of the harms caused by Defendants’ improper distribution practices,” and that retention of that benefit would be unjust. (R. 514 at ¶¶1114-1115; 1108-1121).

The Defendants assert that Plaintiffs do not properly allege that they conferred a benefit upon them. (R. 491-1, PageID# 7519-7522; R.497-1, PageID# 7612; R. 499-1, PageID# 7705-7706). The Distributors argue that under Ohio law, “[i]t is not enough that a plaintiff suffers a loss and defendant receives a benefit; rather, ‘a plaintiff must establish that a benefit has been conferred upon that defendant *by that particular plaintiff.*’” (R. 491-1, PageID# 7520-21) (quoting *Ohio Edison Co. v. Direct Energy Bus., LLC*, 2017 WL 3174347, at *3 (N.D. Ohio July 26, 2017) (emphasis in original); *Bihn v. Fifth Third Mortg. Co.*, 980 F. Supp. 2d 892, 904 (S.D. Ohio 2013)). Moreover, the Distributors construe *Johnson v. Microsoft Corp.*, 834 N.E.2d 791, 799 (Ohio 2005) and its progeny to announce a “rule of law” holding that unjust enrichment claims may only be sustained if they arise from an economic transaction between the parties.⁵⁷ (R. 491-1, PageID# 7520-21; R. 744, PageID# 17675-17676).

⁵⁷ The Manufacturers raise this same argument, citing *Randleman v. Fid. Nat’l Title Ins. Co.*, 465 F. Supp. 2d 812, 824 (N.D. Ohio 2006) in support. (R. 499-1, PageID# 7706).

Plaintiffs assert *Ohio Edison* is distinguishable, arguing that this case does not raise the same concerns—namely, an inability to allocate benefits and losses where multiple actors bought and sold from each other in a complicated market. They also argue that *Johnson* “is even farther afield” because its concern was that indirect purchasers would invoke unjust enrichment to accomplish an end-run around antitrust laws limiting recovery to direct purchasers. According to Plaintiffs, the reasoning does not mandate the same privity in this case. (R. 654, PageID# 15808). In the present action, Plaintiffs’ theory of recovery is not based on a financial transaction, therefore the claim is not barred by *Johnson*’s limiting indirect purchasers from maintaining unjust enrichment claims against parties other than those with whom they dealt with directly. *Johnson*, 834 N.E.2d at 799.

Further, the Pharmacies argue that the alleged expenditures did not save them any expense or loss, but rather the money benefited Plaintiffs’ residents by increasing healthcare services and addiction treatment for opioid users. *City & Cty. of San Francisco v. Philip Morris, Inc.* 957 F. Supp. 1130 (N.D. Cal 1997) (finding that the City could not recover the costs of providing medical care to indigent smokers where there was no allegation that defendant tobacco company had a duty to cover those costs and plaintiff did not show that defendant was enriched); *Ashley Cty., Ark. v. Pfizer, Inc.*, 552 F.3d 659, 666 (8th Cir. 2009) (explaining that Arkansas law only implies a contract to pay for services when they were rendered in expectation of payment from a defendant, and finding that plaintiff had no expectation that the defendant drug manufacturer would pay for municipal services provided in dealing with the methamphetamine crisis). (R. 497-1, PageID# 7612; R. 742, PageID# 17617).

Plaintiffs assert that “[u]njust enrichment arises not only where an expenditure by one

party adds to the property of another but also where the expenditure saves the other from expense or loss.” (R. 654, PageID # 15806-15807, *quoting White v. Smith & Wesson*, 97 F. Supp. 2d 816, 829 (N.D. Ohio 2000) (Nugent, J.)). Therein, the court found that a municipal plaintiff adequately plead an unjust enrichment claim where it was alleged that plaintiff “conferred a benefit upon Defendants, *i.e.*, that the City paid for what may be called the Defendants’ externalities—the costs of the harm caused by Defendants’ [conduct].”).⁵⁸ *Id.* Courts applying *White’s* analysis have arrived at the same result. *See, e.g., City of Los Angeles v. Wells Fargo & Co.*, 22 F. Supp. 3d 1047, 1061 (C.D. Cal. 2014) (citing *White* and finding a sufficient restitution theory where plaintiff alleged the benefits conferred were “externalities—the costs of harm caused by Defendants’ discriminatory lending that the City has had to shoulder”); *City of Los Angeles v. Bank of Am. Corp.*, 2014 WL 2770083, at *12–13 (C.D. Cal. June 12, 2014) (finding a valid claim for unjust enrichment where plaintiff alleged that the defendants’ predatory lending resulted in their enrichment at plaintiffs’ expense, which paid for defendants’ “externalities, or costs of harm caused by its mortgage lending discrimination”); *City of Boston*, 2000 WL 1473568, at *18 (finding plaintiffs stated a claim for unjust enrichment by alleging that they “conferred a benefit upon Defendants by paying for the costs of the harm caused by Defendants’ conduct (“externalities”)”).⁵⁹

⁵⁸ Because the Plaintiffs theory of recovery is not based on an economic transaction, the Distributors assertion that *White* was “effectively overruled” by *Johnson* does not follow. (R. 744, PageID# 17676).

⁵⁹ Plaintiffs also note that potential recovery under unjust enrichment and restitution theories are recognized where third parties have assumed costs of pollution remediation necessitated by defendant activities. *See, e.g., Little Hocking Water Ass’n, Inc. v. E.I. du Pont Nemours & Co.*, 91 F. Supp. 3d 940, 985-986 (S.D. Ohio 2015) (observing that unjust enrichment may serve as an alternative theory of recovery where actual damages are too difficult to determine, but it would be unjust to allow the defendant to benefit from the savings it enjoyed without payment to the plaintiff) (citing cases). (R. 654, PageID # 15807-08).

Distributors also argue that the complaint fails to plead that they had “knowledge” of the claimed benefit allegedly bestowed upon them, maintaining that alleging that “Defendants were aware of these obvious benefits” (R. 514, ¶1115) is too vague and conclusory to state the element. (R. 491-1, PageID# 7521). An identical allegation has been recognized by this court as adequately supporting the unjust enrichment element of knowledge at the pleading stage. *White*, 97 F. Supp. 2d at 829. Distributors further argue that no injustice occurred because Plaintiffs are responsible for the alleged social service expenditures, but cite no authority for that proposition. (R. 491-1, PageID# 7522). Conversely, the *White* decision rejected a similar argument noting that “Defendants fail to cite a single case from Ohio that even comes close to advocating [the] view” that a municipality should be prohibited from recovering “for all governmental functions, such as police, medical, fire and emergency services, and other related expenditures, because these are the kinds of traditional services and functions that a municipality is expected to provide and which are most efficiently and fairly spread among the public.” 97 F. Supp. 2d at 821-822 (internal quotations omitted). Here, the complaint pleads that the costs Plaintiffs assumed “are not part of the normal and expected costs of a local government’s existence,” and that “Defendants’ alleged wrongful acts are neither discrete nor of the sort a local government can reasonably expect.” (R. 514, ¶¶1118-1119).

Finally, the Defendants contend the claim should be dismissed, arguing they are derivative of Plaintiffs’ other claims, and would permit ““an end run around policies’ barring a plaintiffs’ other failed claims.” (R. 491-1, PageID# 7519-7520, *citing Johnson*, 834 N.E.2d at 799; R. 499-1, PageID# 7705). While that proposition is correct, the propriety of any application

to this case would be determined at a later stage of these proceedings. In addition, multiple causes of action based on the same conduct may be asserted alternatively. *PCA Minerals, LLC v. Merit Energy Co., LLC*, 725 F. App'x 342, 349 (6th Cir. 2018) (“nothing prohibits a plaintiff from pleading multiple claims when there are...multiple theories...that are legally viable and consistent with the facts; where a plaintiff has a contract claim, tort claim, and a claim for statutory violation, all may be pled”); *Hutchings v. Nationstar Mortg. LLC*, 2013 WL 5670939 (N.D. Ohio Oct. 16, 2013) (“[A] plaintiff is not precluded from arguing or pursuing multiple theories in the alternative throughout the course of the litigation.”); *Auto Chem Labs., Inc. v. Turtle Wax, Inc.*, 2008 WL 4372697, at *15 (S.D. Ohio Sept. 23, 2008) (“[A] party may plead alternative causes of action for the same matter, but may only prevail under one or the other.”).

Based on the alleged facts in this case, Plaintiffs state a facially plausible unjust enrichment claim on the theory that they conferred a benefit upon all Defendants by alleging that they paid for the cost of harm caused by the defendant’s conduct, *i.e.*, the defendant’s externalities. *See, e.g., City of Everett v. Purdue Pharma L.P.*, 2017 WL 4236062, *9 (W.D. Wash. Sept. 25, 2017) (finding that plaintiffs’ unjust enrichment claim based on their payment of the “so called externalities” of a defendant’s conduct was not facially implausible). Accordingly, it is recommended that the court deny the motions to dismiss Count Ten of the complaint.

K. Count Eleven: Civil Conspiracy

Count Eleven of the complaint alleges a civil conspiracy claim against all Defendants. (R. 514, PageID# 11237). “An underlying unlawful act is required before a civil conspiracy claim can succeed.” *Williams v. Aetna Fin. Co.*, 700 N.E.2d 859, 868 (Ohio 1998). “Conspiracy in and of itself does not normally establish a basis for recovery in a civil action in Ohio; rather, there must be an actionable wrong committed as a result of the conspiracy.” *Glassner v. R.J. Reynolds*

Tobacco Co., 223 F.3d 343, 354 (6th Cir. 2000) (*quoting NPF IV, Inc., v. Transitional Health Servs.*, 922 F. Supp. 77, 83 (S.D. Ohio 1996)); *Hale v. Enerco Grp., Inc.*, 2011 WL 49545, at *5 (N.D. Ohio Jan. 5, 2011) (reciting the elements of a cognizable conspiracy claim as “(1) a malicious combination; (2) two or more persons; (3) injury to person or property; and (4) existence of an unlawful act independent from the actual conspiracy”) (citation and internal quotation marks omitted).

1. Unlawful Acts

Defendants argue that the cause of action should be dismissed “for failure to allege any actionable underlying tort” or an “underlying unlawful act.” (R. 491-1, PageID# 7524; R. 497-1, PageID# 7613; R. 499-1, PageID# 7706-7708). With respect to the Manufacturers, as addressed above, Plaintiffs have sufficiently pled a claim for fraud—an intentional tort. In *Williams*, the Ohio Supreme Court found that the evidence supported a finding of a civil conspiracy where the defendants committed a fraud upon the plaintiff. 700 N.E.2d at 869. With respect to the other Defendants, Plaintiffs also note that under Ohio law, “the unlawful acts of any one member of the conspiracy will satisfy the underlying unlawful act requirement”. (R. 654, PageID# 15814, *quoting Hale*, 2011 WL 49545, at *5 (citations and internal quotation marks omitted); *Williams*, 700 N.E.2d 868 (“[i]n a conspiracy, the acts of co-conspirators are attributable to each other.”)). They contend that the complaint, moreover, alleges facts demonstrating that *each* Defendant engaged in unlawful acts supporting the causes of action therein. With the exception of the negligence claim, each of Plaintiffs’ claims is based on alleged wrongful acts pursued “purposely, without a reasonable or lawful excuse” and therefore may serve to fulfill the underlying unlawful act element. *See Williams*, 700 N.E.2d at 868. Thus, the statutory public nuisance, Ohio RICO, and injury through criminal acts claims would also suffice.

2. Conspiratorial Agreement

Likewise, the Defendants' arguments that a conspiratorial agreement or malicious combination has not been alleged is not well taken. (R. 491-1, PageID# 7522-7524; R. 497-1, PageID# 7613-7614; 499-1, Page ID#7707). Pleading the existence of a malicious conspiracy requires "only a common understanding or design, even if tacit, to commit an unlawful act." *Gosden v. Louis*, 687 N.E.2d 481, 496-98 (Ohio Ct. App. 1996). "All that must be shown is that ... the alleged coconspirator shared in the general conspiratorial objective" *Aetna Cas. & Sur. Co. v. Leahey Const. Co., Inc.*, 219 F.3d 519, 538 (6th Cir. 2000) (citation and internal quotation marks omitted). Direct evidence of an express agreement to undertake unlawful activity is rare and not required; a party may rely on circumstantial evidence to prove the claim. *Weberg v. Franks*, 229 F.3d 514, 528 (6th Cir. 2000). The complaint alleges,

Defendants conduct in furtherance of the conspiracy described herein was not mere parallel conduct because each Defendant acted directly against their commercial interests in not reporting the unlawful distribution practices of their competitors to the authorities, which they had a legal duty to do. Each Defendant acted against their commercial interests in this regard due to an actual or tacit agreement between the Defendants that they would not report each other to the authorities so they could all continue engaging in their unlawful conduct.

(R. 514 at ¶1130, *see also* ¶¶552-553, 764-766). Plaintiffs note that conduct against economic self-interest is recognized as a "plus factor" that may support the plausibility of alleged conspiratorial behavior. (R. 654, PageID# 15812, citing *In re Polyurethane Foam Antitrust Litig.*, 152 F. Supp. 3d 968, 989 (N.D. Ohio 2015)). Furthermore, the complaint alleges that Defendants worked together to manipulate quotas (R. 514 at *e.g.* ¶¶526-528, 548, 550), and that their failure to comply with diversion prevention obligations (*id.*, *e.g.*, ¶¶551-553, 565-566, 611-619) were mutually beneficial to all Defendants in the scheme to expand the opioid market (*id.*, *e.g.* ¶¶760-766). The court has also discussed above the many allegations that the three sets of

Defendants acted in concert and need not repeat those discussions here. Although Defendants fault Plaintiffs for not pleading with pinpoint accuracy, it is alleged that Defendants' activities were clandestine and hidden from the public. Prior to discovery, such precision cannot reasonably be expected, and Defendants' position goes well beyond the *Twombly* and *Iqbal* pleading requirements. Defendant's motion to dismiss Count Eleven should, therefore, be denied.

L. Statewide Concern Doctrine

The Manufacturers and Distributors argue that Plaintiffs' claims should be dismissed under the "statewide concern" doctrine, which "is a fundamental principle of Ohio law that... a municipality may not, in the regulation of local matters, infringe on matters of statewide concern." *Reading v. Pub. Util. Comm.*, 846 N.E.2d 840, 845-46 (Ohio 2016) (quoting *State ex rel. Evans v. Moore*, 431 N.E.2d 311 (Ohio 1982) (prevailing-wage law superseded local wage regulation)); *see also State ex rel. Villari v. Bedford Hts.*, 465 N.E.2d 64 (Ohio 1984) (calculation of employee benefits), *overruled on other grounds, State ex rel. Adkins v. Sobb*, 496 N.E.2d 994 (Ohio 1986) (vacation-leave credits); *Cleveland Elec. Illum. Co. v. Painesville*, 239 N.E.2d 75 (Ohio 1968) (transmission of electricity through high-voltage lines); *State ex rel. McElroy v. Akron*, 181 N.E.2d 26 (Ohio 1962) (licensing of watercraft). Defendants cite Ohio Supreme Court cases recognizing the general doctrine, but have not cited any Ohio authority holding that the doctrine applies to preclude *lawsuits* brought to vindicate rights under federal or state law. For instance, in *JP Morgan*, an Ohio appellate court refrained from making any ruling on that ground, offering only *dicta* to suggest that litigation might, under certain circumstances, constitute regulation. 2013 WL 1183332, at *6 ("The existence of regulation should not, itself, preclude [a nuisance] cause of action. This will often require more evidentiary development than

available when ruling on a motion to dismiss.”)

Plaintiffs argue that Ohio’s Home Rule Amendment allows a sphere of joint authority where local regulation of police powers can co-exist with state regulation in general matters so long as the local regulation does not conflict with state law. Ohio Const. Art. XVIII, § 3; *American Financial Service Ass’n v. Cleveland*, 858 N.E.2d 776, 784 (Ohio 2005). Plaintiffs assert that they possess police powers, including the power to “adopt and enforce local health and safety measures” in order to “protect the public health, safety, or morals, or the general welfare of the public.” *See Marich v. Bob Bennett Constr. Co.*, 880 N.E.2d 906, 911 (Ohio 2008). Therefore, Plaintiffs argue that this litigation presents no conflict with state law.

The Ohio Supreme Court has explained that even where the doctrine applies, it does not trump the state constitutional authority of municipalities to enact legislation pursuant to the Home Rule Amendment, provided that the local legislation is not in conflict with general laws. *American Financial Services*, on which Defendants rely, explains that “the Ohio Constitution’s home-rule provision protects municipalities’ authority to govern themselves, and it provides municipalities some authority to control local health and safety matters when the exercise of that authority does not conflict with general laws.” 858 N.E.2d at 784. To determine whether an ordinance is in ‘conflict’ with general laws, “the test is whether the ordinance permits or licenses that which the statute forbids and prohibits, and vice versa.” *Id.* The only such conflicts Defendants mention are with the Ohio Attorney General’s lawsuit over the opioid crisis and Distributors’ unexplained citation to O.R.C. §4729.01. (R. 499-1, PageID# 7662; R. 491-1, PageID# 7515). Defendants argue that if both of these suits proceed, they would impermissibly split the claims at issue and “risk inconsistent rulings and duplicative recoveries....” (R. 499-1, PageID# 7662). Defendants, however, have identified no Ohio Supreme Court authority holding

that, in such context, the statewide concern doctrine bars locally-originated municipal or county lawsuits seeking to remedy alleged injuries within their borders. Dismissal, therefore, is unwarranted.

M. Article III Standing

The Pharmacies move to dismiss the complaint on the ground that Plaintiffs lack standing under Article III of the U.S. Constitution. (R. 497-1, PageID# 7595-7598). Article III standing requires: (1) an “injury in fact” (2) that is “fairly traceable to the challenged actions of the defendant, and not the result of the independent action of some third party not before the court” and (3) that is “likely to be redressed by the requested relief.” *Bank of Am. Corp. v. City of Miami*, 137 S. Ct. 1296, 1302 (2017); *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). The Pharmacies assert that Plaintiffs have not suffered an “injury in fact” but only a “generalized grievance” and that Plaintiffs’ injury is not “fairly traceable” to the Pharmacies’ conduct. (R. 497-1, PageID# 7596-7597). They do not contest the third element.

1. Injury in Fact

For purposes of Article III standing, an injury cannot be based on a “generalized grievance” that “no more directly and tangibly” affects the plaintiff “than it does the public at large.” *Lujan*, 504 U.S. 555 at 574-575. Cases assessing “generalized grievances” typically involve citizens challenging the propriety of governmental action. *Id.* at 573, 576. The cases the *Lujan* court used to illustrate what is meant by “generalized grievance” involved taxpayer lawsuits—not suits brought by governmental entities. *See, e.g., Valley Forge Christian Coll. v. Ams. United for Separation of Church and State, Inc.*, 454 U.S. 464, 474 (1982) (no standing where taxpayer sued Department of Health, Education and Welfare for allegedly discounted conveyance of government property to a Christian college); *U.S. v. Richardson*, 418, U.S. 166

(1974) (holding taxpayers’ challenge to the government’s failure to disclose CIA expenditures was a “generalized grievance”). *Lujan* itself involved a suit by an environmental advocacy organization challenging a rule promulgated by the Secretary of the Interior, ruling that plaintiffs had alleged an injury to the species in question, but not to themselves. 504 U.S. 555 at 577-578.

The Defendants rely on *Richardson* and *Coyne v. American Tobacco Co.*, 183 F.3d 488 (6th Cir. 1999) to support their conclusion that Plaintiffs allege only a generalized grievance. (R. 497-1, PageID# 7596). In *Coyne*, two Ohio local officials sued tobacco companies as private citizens—not in their representative capacities—alleging that the tobacco companies had caused the State of Ohio to expend public funds on health care costs caused by tobacco-related illnesses. *Id.* at 491. The Sixth Circuit held that these plaintiffs had asserted harms that affected the State as a whole and thus had only asserted a generalized grievance. The Pharmacies argue that Plaintiffs’ alleged harms are like those in *Coyne*.

The court is not persuaded that Plaintiffs have alleged only a “generalized grievance.” The plaintiffs in *Coyne*, *Lujan*, *Richardson*, and *Valley Forge Christian College* lacked standing because, as taxpayers, their harms were no different from those of all taxpayers. This is not the case here. Plaintiffs’ allegations of extraordinary increases in public expenditures on hospitals, law enforcement, emergency and first responders, treatment of infants born with opioids-related medical conditions, and the criminal justice system constitute injury in fact. (R. 514 at ¶948).

2. Fairly Traceable

The Sixth Circuit has recently addressed the “fairly traceable” prong of the Article III standing test, explaining that it is a lower standard than proximate cause. *Parsons v. U.S. Dep’t of Justice*, 701 F.3d 801 (6th Cir. 2015). The *Parsons* court noted that “even an attenuated line of causation to the eventual injury” would suffice. *Id.* at 713; *United States v. Students Challenging*

Regulatory Agency Procs. (SCRAP), 412 U.S. 669, 688 (1973). The court explained that causation in this context “means more than speculative, but less than but-for.” *Parsons*, 801 F.3d at 714. In short, so long as the causal link is more than merely speculative, a plaintiff’s injuries will be deemed fairly traceable to the actions of the defendant.

The Pharmacies argue that any link between Plaintiffs’ alleged harm and their own alleged failure to monitor and report suspicious orders is wholly speculative and does not meet even the relaxed standard of causation associated with the “fairly traceable” requirement for Article III standing. Plaintiffs have alleged that all Defendants, including the Pharmacies, failed to monitor, report, and prevent the diversion of prescription opioids and that this failure has caused Plaintiffs to incur extraordinary municipal costs. (R. 514 at ¶¶555-556, 579-606, 607-659, 934). The court finds these allegations are sufficient. Because Plaintiffs have plausibly pleaded an injury in fact that is fairly traceable to the actions of Defendants, the claim that Plaintiffs lack Article III standing to bring this action should be denied.

IV. Conclusion

After fully considering the second amended complaint and the memoranda in support and against dismissal, it is recommended that the Manufacturers’, Distributors’ and Pharmacies’ separate Motions to Dismiss (R. 491, R. 497, R. 499) be GRANTED in part and DENIED in part. Specifically, it is recommended that the motions be GRANTED with respect to the common law absolute public nuisance claim contained in Count Six, and GRANTED with respect to the

City of Akron's statutory public nuisance claim in Count Five to the extent it is based on violations of Ohio or federal drug laws, or the rules of the board of pharmacy. In all other respects, it is recommended that the motions be DENIED.

s/ David A. Ruiz
David A. Ruiz
United States Magistrate Judge

Date: October 5, 2018

OBJECTIONS

Any objections to this Report and Recommendation must be filed with the Clerk of Courts within fourteen (14) days after the party objecting has been served with a copy of this Report and Recommendation. 28 U.S.C. § 636(b)(1); Local Rule 72.3(b). Failure to file objections within the specified time may waive the right to appeal the district court's order. See *United States v. Walters*, 638 F.2d 947 (6th Cir. 1981); *Thomas v. Arn*, 474 U.S. 140 (1985), *reh'g denied*, 474 U.S. 1111 (1986).